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KWAME OHENE BUABENG

The Role of the Pharmaceutical Sector in Malaria Control in Ghana

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KWAME OHENE BUABENG

The Role of the Pharmaceutical Sector in Malaria Control in Ghana

Doctoral dissertation

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ABSTRACT

Background: Malaria is endemic in Ghana, and contributes significantly to infant and maternal deaths, as well as to loss of disability adjusted life years. The pharmaceutical sector and in particular the medicine outlets has been identified as accessible units in the health system, where public health initiatives could be targeted to facilitate greater access to interventions for prevention and control of malaria. This study was aimed at assessing medicine outlets and their staff in both public and private sector facilities in Ghana, and how their activities conformed to global and national initiatives for malaria control.

Materials and Methods: A preliminary study on the appropriateness of self care and health facilities based management of malaria, and the role played by medicine outlets staff in the supply and utilisation of anti-malarials, was done in a well resourced rural hospital and a city based polyclinic in Southern Ghana. After which an indicator-based assessment of the infrastructure and settings for pharmaceutical services, the staff and material resources and practices for malaria control was done, in a cross section of medicine outlets (n=130) selected from hospitals/clinics and community-based retail outlets in Northern and Southern Ghana. The study indicators were based on international and national standards for pharmaceutical services, as well as the roll back malaria and national policy initiatives for malaria control.

Results: The preliminary study indicated high prevalence of inappropriate use of anti-malarials among those who attempted self care before visiting the health facilities, consequently resulting in severe and complicated malaria conditions that were managed appropriately in the health facilities. The later study showed that the infrastructure and practice settings assessed were satisfactory, but could be further improved and utilized as supplementary or alternative channels to facilitate access to effective interventions for malaria control. On the availability and supply of medicines for malaria therapy; non-policy recommended and mostly ineffective anti-malarials were observed to be highly available and often supplied for malaria therapy, particularly in the retail outlets. The availability of policy-recommended medicines and in particular the artemisinin-based combination products, were rather poor. In addition very few of the outlets (less than 10%) strictly adhered to policy recommendations for the selection and supply of medicines for malaria therapy. On the staff resources; greater than 55% had no professional training as pharmaceutical service providers. The hospitals/clinics had more professional staff per outlet than those in the retail sector. Majority of the staff assessed (over 80%), which included both professionals and non professionals could recognise malaria illness and also advice clients on how to avoid further infections. However, very few (20%) and mainly professionals were adequately skilled to both recognise and manage the malaria cases as recommended by national guidelines.

Conclusions: The infrastructure and settings in most of the outlets were satisfactory for pharmaceutical services. However, there were significant shortfalls, regarding the availability and supply of effective medicines for malaria control. Also majority of the staff assessed were inadequately skilled to appropriately manage malaria cases. Pragmatic education and regulatory interventions should be directed towards the pharmaceutical sector to improve the availability and accessibility of safe and effective medicines, and also adequately resourced personnel to support national initiatives for malaria control.

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Dedicated to my family in Ghana.

I am really sorry for being an absentee husband, father, uncle, big brother and son.

I appreciate all the support and your understanding.

KOB

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Kuopio, January 2010

K. Ohene Buabeng

LIST OF ORIGINAL PUBLICATIONS

This doctoral thesis is based on the following original publications, referred in the text by Roman numerals **I –IV**.

I Buabeng K O, Duwiejua M, Dodoo A N O, Matowe L K, Enlund H. Self-reported use of antimalaria drugs and health facility management of malaria in Ghana. Malaria Journal 6: 85, 2007

II Buabeng K O, Duwiejua M, Matowe L K, Smith F, Enlund H. Availability and Choice of Anti-malarials at Medicine Outlets in Ghana: The question of access to effective medicines for malaria control. Clinical Pharmacology & Therapeutics 84: 613–619, 2008

III Buabeng K O**,** Matowe L K, Smith F, Duwiejua M, Enlund H. Knowledge of medicine outlets' staff and their practices for prevention and management of malaria in Ghana. Pharmacy World Science 2009; Accepted for publication, 30th September 2009

IV Buabeng K O, Matowe L K, Smith F, Duwiejua M, Ahonen R, Enlund H. The infrastructure of Ghanaian medicine outlets and its suitability to support public health initiatives and services for malaria control. Submitted

CONTENTS

LIST OF ABBREVIATIONS

ACTs – Artemisinin-based Combination Therapy
AIDS – Acquired Immune Deficiency Syndrome
CIDA – Canadian International Development Agency
CBMIS – Community-Based Mutual Insurance Schemes
DANIDA – Danish International Development Agency
DFID – Department for International Development, UK
FDB – Food and Drugs Board
FIP – International Pharmaceutical Federation
GNDP – Ghana National Drugs Programme
GHS – Ghana Health Service
GPP – Good Pharmacy Practice
MHOs – Mutual Health Organisations
HIV – Human Immuno-deficiency Virus
IPTi – Intermittent preventive therapy in infants
IPTp – Intermittent preventive therapy in pregnancy
ITN – Insecticide Treated bed Nets
JICA – Japanese International Co-operation and Development Agency
KBTH – Korle-Bu Teaching Hospital
KNUST – Kwame Nkrumah University of Science and Technology
LCS – Licensed Chemical Sellers Shop
MDC – Medical and Dental Council
MTHS – Medium Term Health Strategy
MOH – Ministry of Health, Ghana
MSH – Management Sciences for Health
NGO – Non Governmental Organisation
NHIS – National Health Insurance Scheme
NMCP – National Malaria Control Programme
OPD – Out-Patient Department
OTC – Over the Counter Drugs

PSGH – Pharmaceutical Society of Ghana

RBM – Roll Back Malaria

SEAM – Strategies for Enhancing Access to Medicines

STG – Standard Treatment Guidelines

STI – Sexually Transmitted Infections

TMPs – Traditional Medical Practitioners

UNICEF –United Nations and International Children's Fund

USAID – United States AID and Development Agency

URTI – Upper Respiratory Tract Infection

WHO – World Health Organisation

1 INTRODUCTION

Pharmacists around the globe are increasingly getting involved in health promotion, in addition to supplying medicines and counselling patients and the general public on rational use of medicines (Schnipper et al 2006, Wiedenmayer et al 2006, Smith 2009a). The overriding objectives of these duties are to help patients/clients to have best outcomes from drug therapy and pharmaceutical services, and to live a healthy life (FIP 1997b, Anderson 2002,). In Ghana (formerly Gold coast), the delivery and regulation of pharmaceutical services dates back to 1892, with the promulgation of druggist ordinance and later the dangerous drugs ordinance in 1935. The services available at the time were dispensing of prescriptions and making extemporaneous preparations, upon the requests of medical practitioners. The focus for pharmaceutical services in Ghana has evolved as in many parts of the world, with practitioners being urged to deliver services that are centred on patient's health and pharmaceutical care needs (Canadian Pharmacists Association 2004, Smith 2004, Wiedenmayer et al 2006).

Ghana is a small West African country bordered on the west by Cote d'Ivoire, the north by Burkina Faso, east by Togo and south by the Atlantic Ocean. It covers an area of about 284,000 square kilometers and has a population of about 23million. Thirty eight percent of the population are below the age of 15 years, 58% are between the ages of 15 to 64years and 4% are 65 years and above. Life expectancy at birth is about 59 years, 58 for men and 60 for women (CIA World fact book 2008). English is the official language of instruction and teaching in schools, and close to 58% of the population above the age of 15 years are literate (66% for males and 50% for females).

Ghana is as a low income country with a GNI per capita of $ 1430 (CIA World fact book 2008). The total expenditure on health per capita in 2005 was about $100, and the average expenditure on health as percentage of GDP was about 6.2. Government expenditure on health as proportion of the total health expenditure was 34%, whilst that of private expenditure on health was 66% (WHOSIS 2006). Of the private expenditure on health, close to 80% is believed to be funded out of pocket, and significant proportion of this may be expenditure on pharmaceuticals (Republic of Ghana 2002, GNDP 2004).

As typical of countries in sub-Saharan Africa, many of the diseases that are prevalent and mostly responsible for deaths and disabilities in Ghana are preventable and also curable. A typical example is malaria, which accounts for over 23% of deaths in children under five years of age, and close to 10% of all deaths in pregnant women annually (Malaria Operational Plan–FY08, MOH 2006). Many researchers and advocates for health in low income countries recommends that adopting multi-sectoral approaches towards the implementation of public health initiatives, and appropriately developing and utilizing the skills of all service providers in the health system may be an effective means to reduce the burden of diseases of curable and preventable causes (Smith 2004, Snow et al 2005, Ndomongo-Sigonda et al 2005). The purpose of this study was to assess the infrastructure, settings for pharmaceutical services and practices for the prevention and control of malaria in medicine outlets in the Ghanaian health system, and thus make recommendations on how the pharmaceutical sector could be effectively involved in malaria control and other primary health care initiatives in Ghana.

2 BACKGROUND

Searches were done in Pubmed, International Pharmaceutical Abstracts, Web of Science and Google for background literature about health, health care challenges and the contribution of pharmaceutical sector in resolving public health challenges in sub-Saharan Africa, including the prevention and control of malaria, and with particular focus on Ghana. The search words included: health, health care, health policy, drug policy, malaria prevention, control and anti-malarial therapy. These were matched against key words such as sub-Saharan Africa, West Africa, Ghana, pharmaceutical sector, pharmaceutical services, medicine outlets, medicine sellers, medicines supply management, malaria therapeutic practices etc. Initially the search was limited to literature that was published in the last five years; but not much relevant literature was obtained, therefore search was extended to published articles in the last 10 to 15 years. Still, when limited literature was found on topics like health policy, pharmacy education in Ghana and public health responsibilities of pharmacy practitioners, the web sites of the Ministry of Health (MoH), Ghana Health Service (GHS) and that of Kwame Nkrumah University of Science and Technology (KNUST) were consulted. The information obtained from these sites was more descriptive and mostly oriented at advertising the institutions. However, the website of Management Sciences for Health (MSH), an international NGO with interest in strengthening health systems and management practices in resource poor countries, as well as that of World Health Organisation (WHO) and Centre for Disease Control and Prevention (CDC) were also searched for more information on the pharmaceutical sector and their contribution to public health initiatives and interventions for malaria control in Ghana or the West Africa sub-region.

2.1 Health and health care challenges in sub-Saharan Africa

The predominant challenges to health and health care in sub-Saharan Africa are infectious and parasitic diseases; among which HIV/AIDS, tuberculosis (TB) and malaria together are estimated to cause about 6 million deaths per annum (Quick et al

2005, Dräger 2006). Other infectious diseases of public health interest include: urinary tract infections, pneumonia and other acute respiratory infections and gastro-intestinal infections that are closely linked to poor hygiene and environmental sanitation (WHO 2006). Beside the infectious diseases, nutrition related and non-communicable diseases like anaemia, hypertension, diabetes and complications from these are also known to contribute significantly to deaths and disabilities in sub-Saharan African (Goodburn et al 2001, Kadiri 2005, Sanders et al 2005). Coupled to the diseases from communicable and non-communicable causes, there are socio-economic and political challenges that influence directly or indirectly on the health of people in sub-Saharan Africa. These include illiteracy, poverty, civil wars, poor access to safe and effective medicines, poor access to portable water and nonexistent or under resourced health care facilities. The occurrence of these challenges and its impact on individual and population health may vary from country to country depending on functionality of the health systems, the availability and use of resources for health and the political situation in the respective countries. This is usually reflected on health indicators like life expectancy at birth, potential years of life lost and GNI per capita (Sanders et al 2005, WHO 2006).

On human resources for health, the available evidence suggests that many low income countries are having difficulties in keeping professionally trained and skilled personnel in their health facilities. This situation is particularly acute in the deprived and rural areas in sub-Saharan Africa, and is largely blamed on the availability of weak or nonexistent structures for health care and other supportive social services. This has led to the refusal of many skilled and professional personnel to accept postings to the rural areas as health workers. There is also the evidence of emigration of highly trained and skilled professionals from low income countries to rich and industrialised countries to seek for better opportunities in life and in their professional career (Smith 2002, Matowe et al 2004, Chan 2006).

Since the 1980's several developmental projects have been undertaken to improve the health and socio-economic challenges in sub-Saharan Africa. Most of the projects have been supported technically and financially by international organisations and donors like WHO, UNICEF, World Bank, USAID, CIDA, DFID, DANIDA, JICA etc, and also by NGO's and philanthropists including MSH, the Clintons and Bill and

Melinda Gates Foundations. Priority areas that have been focused in some of the above mentioned projects included HIV/AIDS, malaria and TB control. Others were programs targeted to improve reproductive and child health, environmental sanitation, access to portable water and essential medicines (Sanders 2005, Quick et al 2005, Ooms 2006). Health reports in countries where some of the above mentioned projects had been undertaken, have suggested marginal improvements in health outcomes on infant and maternal deaths, premature deaths and the quality of medicines use in public health care facilities (Republic of Ghana 2002, Cohen et al 2005, WHO 2006). Notwithstanding the reported improvements, the health status of many countries in sub-Saharan Africa is still counted among the worst in the world (Cohen et al 2005, Quick et al 2005).

On access to medicines, the WHO estimates suggests that over 250 million people in sub-Saharan Africa still lack regular access to the most essential medicines for common health problems (Ooms 2006, WHO 2006). There are also concerns as to whether the health gains that have been reported in countries like Ghana could be sustained over a long period of time, if the health initiatives tested and shown to be working are not efficiently implemented for greater access (Quick et al 2005, Sanders et al 2005). It is believed that the pharmaceutical sector could play a useful role, if the human resources are appropriately equipped with the needed skills for safe primary care services, and integrated into programs/schemes designed to promote health, and to reduce deaths and disorders from preventable and treatable causes (Adu-Sarkodie et al 2000, FIP 1997a, Smith 2002, Quick et al 2005).

2.2 Pharmaceutical services and health in Societies in sub-Saharan African

Community Pharmacies and other retail medicine outlets in sub-Saharan Africa have been noted as the first port of call for many individuals seeking medication and primary care services for common complaints and symptoms like fever, bodily pains, coughs etc (Goodman et al 2007a,Viberg et al 2007, Smith 2009b). This situation may in part be due to the low number of formal health care facilities available in the system, and/or problems of geographic and financial access to the few publicly funded hospitals and clinics. Accessing primary care services for conditions like malaria, diarrhoea and other

common conditions from medicine outlets could therefore be of strategic importance to public health, if the services are delivered according to some quality standards and with focus on patron's safety (FIP 2005, WHO 2006, Chandler et al 2008). In many sub-Saharan African countries including Ghana, the health/drug legislations and policies support the need for pharmacists and pharmaceutical service providers to give health advice and basic primary care services against common health complaints and symptoms, in addition to the traditional medicines management and dispensing services (GNDP 2004).

A major challenge to efficient primary care and safe pharmaceutical practices in the medicine outlets may be the availability of pharmacists and other professionally trained pharmaceutical workers. In African and other low income countries, pharmacies and services of pharmacists are mainly concentrated in the cities and urban areas. This situation is believed to be the result of not having adequate numbers of pharmacists in these countries, and thus making it difficult for the pharmacists to extend their services to every part of the respective countries (Chan 2006, Viberg et al 2007). For example by December 2005, the number of pharmacists that were registered by Pharmacy Council in Ghana was 2162. Of this 30% were estimated to be living or practising in Europe, US and other high income countries, suggesting a pharmacist: population ratio of less than 1:10,000. Since the factors that contributed to the emigration of skilled professionals still exist, the pharmacist/population ratio that prevails today may not be significantly different from that in 2005 (Duwiejua et al 2004, Owusu-Daaku et al 2008).

In the war torn and least developed African countries, the pharmacists/population ratio is even believed to be worse than that of Ghana i.e. less than 1:100,000 (Viberg et al 2007). In addition to non-availability of pharmacists, pharmacy businesses are also believed to be uneconomically viable in poor settings like that of the deprived and rural areas in sub-Saharan Africa (Chan 2006, WHO 2006). In such settings the main sources of medicines and other health commodities are non-pharmacy retail outlets, general shops and sometimes unregistered or unlicensed itinerant drug peddlers (SEAM 2003, Smith 2004, Goodman et al 2005). In Ghana, the MOH, health professional groups like the Medical Association and Pharmaceutical Society, and the regulatory authorities try

to educate and discourage the public to avoid the itinerant drug peddlers, whose services are considered unsafe and illegal (GNDP 2004, MOH 2006).

Apart from the illegal and unsafe practices from drug peddlers, several concerns have also been expressed by many health stake holders on the quality and safety of services that are delivered in registered medicine outlets, particularly those in the retail sector and their public health implications. The reasons being that, many of the retail outlet practitioners may not be adequately trained, or may have inadequate knowledge about the risks and biological effects of the medicines they recommend or supply for the management of common health complaints (Smith 2002, Goodman et al 2007a, Smith 2009a). In addition the practitioners may not be adequately skilled to provide appropriate primary care services, and could possibly harm their patrons and the public with their services (SEAM 2003, Quick et al 2005, Sanders et al 2005).

In Ghana, Nigeria and some Eastern African countries like Kenya, Ethiopia and Tanzania, the MSH through its Strategies for Enhancing Access to Medicines (SEAM) project, undertook training interventions to improve the quality of primary care services in registered retail medicine outlets. The outcomes of the project showed that with appropriate training and motivation, the practitioners in medicine outlets could deliver efficient pharmaceutical/primary care services, and refer cases that are beyond their level of competence to appropriate institutions for better management (Goodman et al 2005, Mbwasi 2005, Hatzel et al 2008a). Unfortunately, not much is known about the extent to which the interventions that were tested in the SEAM project have been rolled out to ensure access to safe primary care services and essential medicines in the rural and remote areas of the respective countries. In order to engage the pharmaceutical sector effectively in primary care initiatives, the capacity of the practitioners must be strengthened to deliver appropriate and safe services. In addition, evaluation research on activities in the sector must be promoted, to generate the needed evidence to guide policies and interventions for best practices (Jones 2003, Quick et al 2005, Dräger et al 2006).

2.3 Health policy of Ghana

Since the 1970's, Ghana's health policy has been based on the principle of Primary Health Care; with the goal of achieving universal access to preventive, curative and rehabilitative services. However implementation of the policies had never been successful up until the late 1990's. The erratic and poor implementations of the policies were attributed to: political instability, inadequate financial and human resources and other factors related to appropriateness of the strategies adopted to achieve the goals. The limited resources available for health were mostly allocated to curative services, leading to weakening of the preventive and rehabilitative services (Rankin et al 1993, Agyepong 1999).

In 1997, a policy termed "Medium Term Health Strategy" was initiated to strengthen primary health care structures and the delivery of services at secondary and tertiary level institutions in the health system (MTHS 1997).

The main approaches of the strategies adopted for policy implementation were:

1) Decentralization of health services management, and services delivery.
2) Adoption of cost sharing and cost recovery programs, with recipients of health care paying out of pocket for services. With this strategy, special arrangements were made to finance services for the very poor and vulnerable groups like the aged (75 years and above), neonates and pregnant women.
3) Prioritizing resource allocation, and targeting mainly essential and cost effective services.
4) Fostering partnership and collaboration between government and other service providers in the private sector to increase access to essential health services (MTHS 1997).

There was evidence that the cost sharing strategy did improve resource generation in health facilities that implemented the policy, and thus enabled them to stock adequate amounts of essential medicines and other medical supplies, needed for the delivery of services (MOH 2006). However many individuals were still denied access to basic health services and essential medicines because of problems of affordability or ability to pay out of pocket (Atim et al 1999, Agyepong et al 2004, Awoonor-Williams et al

2004). Similarly in the 1990's, some non-profit Mutual Health Organisations (MHO) or community-based insurance schemes were experimented by community members and social organisations in places like Kasena Nankana district in Northern Ghana and Nkoranza district in Southern Ghana, to finance important health care services, including malaria therapy. Membership and beneficiaries of the schemes were derived from voluntary individuals, families or social network organisations that were able and willing to pay for the agreed premium, required to finance the scheme and health care services, including the costs of hospitalisation and pharmaceutical services (Atim et al 1999, Chankova et al 2008). Subsequent evaluations had indicated that those schemes provided health security and improved access to health services for its members. However, there were still problems related to lack of access for essential health services to certain poor individuals and families in the districts, who could not join the insurance schemes due to unaffordability of the agreed premium (Chankova et al 2008, Witter et al 2009).

Currently, a new health policy is in place which is basically a review and strengthening of the medium term health policy, which is tied to the development agenda of Ghana, and thence the achievement of the millennium development goals. It is based on the premise that improving the health of the general population and in particular the poor is crucial to achieving accelerated and sustainable economic development. The current policy provides a holistic frame-work for services delivery, in order to improve health outcomes for all Ghanaians. It emphasizes the need to mobilize individuals, health professionals and the general public to promote health and reduce morbidity and mortality from diseases of preventable and treatable causes (Agyepong et al 2004, MOH 2006). The new policy also provides guidelines on how to strengthen the manpower and professional competencies of the health work force to deliver better services. The key question that may be answered through evaluation research is whether the targets outlined in the policy could be achieved, and what role the pharmaceutical sector could play in promoting health, and protecting the public against common diseases like malaria.

Under the new policy, primary health care services, including the supply of essential medicines from accredited medicine outlets, and essential secondary and tertiary health

services, would be financed through a National Health Insurance Scheme (NHIS) for registered members, pregnant women and elderly patients who are 75 years old and above. This was passed into law in 2003 (GNDP 2004, MOH 2006). The NHIS is funded through various taxation mechanisms, including national health insurance levy, which is 2.5% of the value of all items purchased on Value Added Tax (V.A.T). Others are 2% tax deductions from salaries of employees on government pay roll (i.e. the formal sector) as well as parliamentary approved levies imposed on co-corporate institutions, companies etc, and contributions from members/beneficiaries in the informal sector. The beneficiaries in the informal sector, including self employed individuals and their families are supposed to be registered members of NHIS or Community-Based Mutual Insurance Schemes (CBMIS) or private insurance schemes, recognized by the NHIS (GNDP 2004, MOH 2006, Witter et al 2009). The current CBMIS were a modification of the former MHO's, but expanded to be able to mobilize larger proportions of low income individuals and poor families in the communities to membership, in order to ensure improved access to affordable health and pharmaceutical services (MOH 2006, Witter 2009). The CBMIS are financed through funds raised from individual members in the informal sector through a premia (a minimum of 12 US dollars per anum), which is determined in agreement with the National Health Insurance Authority (NHIA). A recent evaluation of the NHIS has shown that current national coverage is around 45% of the population (Witter et al 2009). This suggests that there are still large populations of Ghanaians who are uninsured, and still use out of pocket payments to finance essential health and pharmaceutical services, including services for malaria therapy. This situation may still pose challenges regarding equity and access to essential health services, including specialized health care services that may not covered by NHIS or the private insurance schemes (Busia 2005, Witter 2009).

2.4 Health systems in Ghana and organisation of health services

Health services in Ghana can be accessed from facilities under the two main sectors in the health system (Figure 1); these are the public sector and the private sector. The

private sector is sub-classified into private formal and private informal sectors. The latter comprises of non-pharmacy retail operators, traditional healers, homeopathic operators and traditional birth attendants. It is estimated that about 60% of patient care and other services in the health system, are taken care of by the private sector (Agyepong 1999, GNDP 2004, Cohen et al 2005**)**. However, not many analytical studies have been done on health services delivery in the private sector, and how the services could be optimised to benefit the society (Gonzalez-Block 2004, Kweku et al 2007).

Generally health services in the private sector, are delivered by either private for profit or private not for profit facilities. The for-profit facilities include privately owned hospitals, clinics, maternity homes as well as retail pharmacies. The private not for profit facilities include faith based institutions and NGO's that are involved with health services from hospitals, clinics and primary care facilities. In addition, there are co-operate bodies including corporations and security agencies that have facilities that provide health services for their employees. In some of these institutions, the health services are also accessible to the general public. Not much scientific information, however, is available about the level of co-operation and collaboration that exist between the private and the public sector to achieve common public health goals (SEAM 2003, Agyepong et al 2004, Cohen et al 2005).

As illustrated below in Figure 1, practitioners in the informal sector including Traditional Medicine Practitioners (TMP) have over the centuries and to date been using herbs, other plant products and animal parts, and possibly religious practices (depending on the practitioner) to manage diseases; ranging from common problems like malaria to chronic diseases such as hypertension, diabetes and asthma (Tsey 1997, GNDP 2004, Busia 2005). Some are even known to be involved in the delivery of specialised services like bone setting and management of mental disorders in both urban and rural areas in Ghana (Tsey 1997, Abel et al 2005, Tabi et al 2006). The ratio of TMPs per capita in Ghana is about 1:200, whilst that of trained medical doctors is about 1: 20,000. It is estimated that about 75% of the population in Ghana may still be using the services of TMPs and/or herbal products accessible from unlicensed itinerant peddlers to licensed chemical sellers in the rural areas, and herbal shops or retail pharmacies in the urban

areas, to deal with essential health or primary care needs (Houghton et al 2003, Tabi et al 2006, Goodman et al 2007a). This may be due to the ease of accessibility and affordability of the services of TMPs or the herbal products compared to accessing the health services from the formal sector (Houghton et al 2003, Busia 2005). Some of the practices of TMPs and the products used for healing, especially the herbal or plant products have been authenticated scientifically to have medicinal properties (GNDP 2004, Abel et al 2005). Also significant efforts have been made by the MOH and other stake holders in the health system to enhance research in this area, and to regulate the practices of TMPs, as well as the production of traditional medicinal products and to ensure its rational use. However, there are still scepticism and concerns regarding public health protection and safety after exposure to the practices of some TMPs and the many herbal products that are being actively advertised or promoted in the country for management of all kinds of diseases (GNDP 2004, Abel et al 2005, Busia 2005).

In the public sector, health services are offered through a network of hospitals, clinics and primary care centres. Each of the above mentioned units provide different types of services, depending on the resources available and their human resource capacity. The lower level facilities (sub-district and community health care centres) offer mainly primary health services, whilst secondary and specialist services are provided usually at the district and regional health care facilities. Tertiary health services are available mainly at the teaching hospitals, and also some of the regional hospitals that have the capacity for the services**.** Though there have been reports of some progress in the functionality of public health institutions in Ghana over the last decade (GNDP 2004), the available evidence suggests that serious challenges still prevail that needs to be addressed. These include the availability and retention of motivated and skilled personnel, existence of long waiting hours and perceived poor quality of services in the public sector health facilities (Attipoe 2001, SEAM 2003, Gonzalez-Block 2004, Goodman et al 2007).

The MOH in Ghana has direct oversight responsibility for all programs and activities that are outlined in the health and medicines policies to keep citizens safe and healthy. The MOH takes responsibility for policy formulation, planning, co-ordination, and regulation of all programs, interventions and services in the health system. Ghana

Health Service (GHS), the service delivery arm of MOH is an autonomous agency, established by a parliamentary ACT (ACT 525, 1996**)**. GHS is under the management of a Director-General, who is part of the governing board of GHS Council. GHS has the mandate for the management and delivery of services in public health institutions in the country, with exception of the teaching hospitals. The teaching hospitals are also autonomous, and have their own governing boards. They provide specialists services and to some extent, ambulatory services through their polyclinics. The teaching hospitals serve as referral hospitals for the regional health institutions and others that are outside the public sector. In areas in the country where GHS do not have any health facilities, they contract services to health institutions of the faith based organisations or other institutions that have health facilities to serve the public. Despite the well defined structures in the public health system, there are significant setbacks regarding human and financial resources, as well as inequities in the distribution and accessibility of facilities across the country, with huge disparities between regions, districts, and also the urban and rural areas (SEAM 2003, Kweku at al 2007).

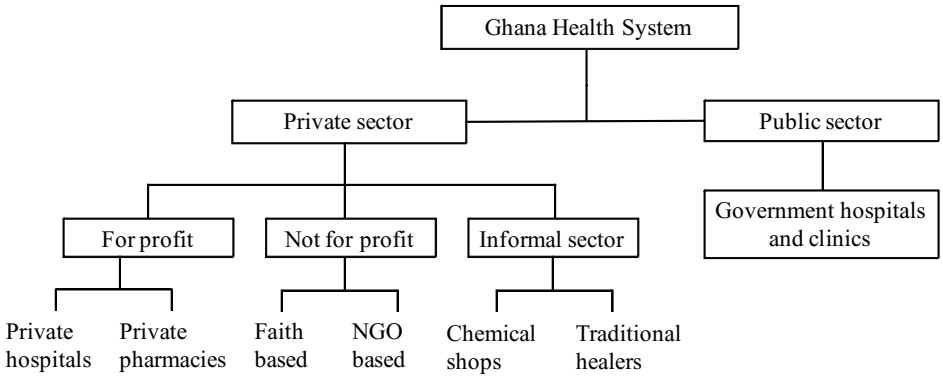

Figure 1. Structure of the Ghana health system.

2.5 Regulation of health and pharmaceutical services

In Ghana, semi-autonomous and government funded institutions that are backed by legislation are responsible for the regulation and enforcement of laws and standards of

practices for health and pharmaceutical services. The Medical and Dental Council for example is responsible for registration, regulation and control of practices of medical doctors and dentists in the country. The Nurses and Midwives Council is also responsible for registration, regulation and control of all activities and practices of nurses and midwives in the health system.

Before the 1990´s, pharmaceutical practices, market authorisation of medicinal products, and other pharmacy related activities in Ghana were regulated by Pharmacy Board under the Pharmacy and Drugs ACT 1961 (Act 64). In the 1990's, the Pharmacy ACT 1994 (Act 489) and the Food and Drugs Law 1992 (PNDCL 305b) were introduced to establish two distinct institutions that had separate functions for the regulation of medicines manufacture, market authorisation, supply chain management and the delivery of pharmaceutical services. The registration of outlets, regulation of services as well as the training of retail outlet practitioners was put under the jurisdiction of Pharmacy Council (Pharmacy ACT 489). The Food and Drugs Board (FDB) regulates and control the activities of companies that manufacture, import and export medicines in and out of the country. The FDB is also responsible for market authorisation of medicines, cosmetics, household chemicals and medical devices that are stocked and utilised in health care facilities and medicine outlets in Ghana. Generally the regulation of health and pharmaceutical services in Ghana, as in many sub-Saharan African countries are known to be inadequate due to limited availability of financial, human and material resources; and this has been identified as a major safety and public health concern (Goodman et al 2007a, Goodman et al 2007b, Smith 2009a).

2.6 The pharmaceutical sector and services of medicine outlets

Like health care services, pharmaceutical services are also provided in the medicine outlets of public and private sector institutions including hospitals/clinics and community-based retail outlets like pharmacies and licensed chemical shops. In the hospitals and clinics, medicines are usually prescribed by clinicians and dispensed by the staff in pharmacies/dispensaries or by the clinicians themselves in small clinics. The clinician may be a medical doctor, medical assistant or a nurse/midwife, depending on

the facility and the scope of services they deliver. The community pharmacies are legally authorized to supply prescription and non-prescription medicines, and also provide primary care services against common complaints and symptoms like fevers, cough and cold. The pharmacies are located mainly in the urban areas where commercial activities are high, and pharmaceutical services also are supposed to be supervised by registered pharmacists. However it is not uncommon to enter pharmacies in many developing countries including Ghana, where pharmacists are not available and services are delivered unsupervised by non-professional sales personnel (Smith 2004, Goodman et al 2007b, Viberg et al 2007). The licensed chemical shops are registered non-pharmacy retail outlets that are authorised to supply essential medicines in the rural and remote areas in Ghana where pharmacy services may not be available. Many licensed chemical shops in Ghana are known to stock and supply prescription medicines including antibiotics; and there are concerns that their services may be harmful to public health since it is largely delivered by non-professional and inadequately trained practitioners (Goodman et al 2007a, Smith et al 2009a).

In the public sector, the head of pharmacy unit is the director of pharmaceutical services or chief pharmacist. The Chief Pharmacist is a key technical advisor to the health minister on matters related to pharmaceutical services. The Chief Pharmacist is also a member of the executive committee of the Pharmaceutical Society of Ghana. In the regions the Chief Pharmacist delegates responsibilities to deputy directors of pharmaceutical services (regional pharmacists), who are integral members of the Regional Health Management Teams (RHMT) of GHS. The regional pharmacists have oversight responsibility for services and practices of all pharmacists, technicians and other workers in the medicine outlets of facilities that are working for the GHS in the region. Generally Pharmaceutical services in the public sector are believed to be more organised and functional than that in the private sector, which is usually driven by profit or business interest (Anderson 2002).

Other stake holders who work collaboratively to assure quality and safety of practices in the pharmaceutical sector are: i) The Pharmaceutical Society of Ghana; of which every registered pharmacist is a member, ii) the directorate in MoH responsible for drug policy, procurement and supply chain management, iii) national regulatory

institutions for the pharmaceutical sector, iv) local industries and agents/wholesaler for multinational pharmaceutical companies and v) the Faculty of Pharmacy at KNUST and other institutions that train workers for the pharmaceutical sector as well as the Association of Licensed Chemical Sellers.

2.7 Medicines supply management chain

About 70% of medicines that are in circulation in Ghana are imported by registered pharmaceutical wholesalers or local agents and distributors for multinational or foreign pharmaceutical companies. The remaining 30% are manufactured by local pharmaceutical companies and supplied to pharmaceutical retailers and healthcare facilities through their wholesale outlets network. In the public sector, pharmaceuticals and other medical supplies are distributed mainly through the Central Medical Store (CMS) to the public institutions, including the teaching hospitals and other not for profit private institutions, that are contracted by GHS. The CMS has sub-branches in the regions for the peripheral health care institutions including clinics and health centers. The CMS operates under the directorate responsible for policy, procurement and supply of essential medicines in the MoH. In the private sector, pharmaceuticals and other health commodities are predominantly supplied or distributed through the wholesale distribution networks of local manufacturers and licensed pharmaceutical importers.

All pharmaceutical products that are stocked and supplied from medicine outlets in Ghana including herbal medicines, are required to be registered and certified by the Food and Drugs Board as safe, effective and of good quality (PNDCL 305b). However, it is not uncommon to find unregistered pharmaceuticals in medicine outlets in many countries in sub-Saharan Africa, including Ghana (Goodman et al 2004, Amin et al 2005). The unregistered medicines are mostly supplied through unlicensed itinerant suppliers to wholesalers or directly to the health facilities. The sources of such unregistered medicines have been identified as neighboring West African countries or agents of pharmaceutical companies abroad (mainly Asia), and in particular India and China, whose products are yet to penetrate the Ghanaian market. The evidence available

indicates a higher likelihood that such products may be fake or substandard, and thus must be avoided (Quick et al 2005).

2.8 Pharmacy education and manpower issues

In the 1890's when pharmacy practice was institutionalised in Ghana, the key practitioners were pharmacists mostly trained in the United Kingdom, and technicians from the dispensary school of Korle-Bu Teaching Hospital (KBTH), Ghana's premier teaching hospital. Pharmacy in Ghana gained public recognition in the mid 1930's as a health profession, when the pharmaceutical society was formed by practising pharmacists at that time, with the support of the Director of Medical Services, MoH. The mission of the pharmaceutical society was to assist the government to institute appropriate education and ethical standards for pharmacy practice in Ghana.

In the early 1950's, students of the dispensary school at KBTH were transferred to a college of technology in Kumasi which was then running a certificate course on pharmaceutical services for the dispensers at a department of pharmacy. In the early1960's, the college was elevated to university status under government ordinance, and was named as Kwame Nkrumah University of Science and Technology, after the first president of the Republic of Ghana. The department of pharmacy then evolved into a faculty, which initially run a two-year comprehensive course for certificate in pharmacy practice. The certificate course was later upgraded to diploma and finally to a Bachelor of Pharmacy degree.

Until recently, the Faculty of Pharmacy at KNUST was the only institution that train pharmacists in Ghana, and credited as one of the oldest pharmacy institutions in Africa. Since the 1960's, KNUST has been offering undergraduate composite pharmacy degree programme, and postgraduate courses in pharmaceutical chemistry, pharmacognosy, pharmaceutics and pharmacology and toxicology. In the early 1990's, an MSc course in pharmaceutical analysis and quality control was introduced to produce quality control experts for the local industries.

In the mid 1990's, after a review of the pharmaceutical sector by local experts and others from WHO and MSH, a national drug policy was developed and launched with the aim of improving the quality of medicines use and pharmaceutical services in Ghana. Part of implementation of the policy led to the establishment of a Department of Clinical and Social Pharmacy at KNUST to strengthen the capacity of practising

pharmacists and pharmacy students to promote the rational use of medicines in Ghana. The department has since introduced courses at both undergraduate and post graduate levels to equip students and practising pharmacists with practical knowledge and skills in public health, pharmacotherapy and pharmaceutical care, to be able to meet the challenges of contemporary practice in pharmacy and pharmacy practice research (Republic of Ghana 2002, Duwiejua et al 2004, GNDP 2004).

Since the year 2000, KNUST have been producing more than 100 pharmacy graduates per year, who (apart from those who emigrate) are employed in various institutions in the health system. The majority of the pharmacists are employed in hospitals and community pharmacies. Other institutions that engage the services of the pharmacists are: the local pharmaceutical industries, multi-national pharmaceutical marketing companies, the regulatory agencies, health oriented NGO's, and the academic and research institutions. There are also reports that close to 30% of the pharmacists that are trained in Ghana, emigrate to industrialised countries in Europe, North America or Australia to either pursue post graduate studies or register with the pharmaceutical associations and practice as pharmacists or pharmacy technicians (Matowe et al 2004, Chan 2006).

In addition to KNUST, Kumasi Polytechnic, a publicly funded college, train dispensing technologists and technicians who provide technical support services for pharmacists in the hospitals, community pharmacies and in manufacturing industries. The dispensing technologists are holders of Higher National Diploma (HND), where as the dispensing technician course is a certificate programme offered by the polytechnic. Apart from the pharmacists, dispensing technologists and technicians, there are a large number of non-professionally trained practitioners that are involved with the provision of pharmaceutical services. These practitioners may be trained as medicine counter assistants by institutions (usually private) accredited by Pharmacy Council, or may have had on the job training by pharmacists/technicians or the owner of the pharmaceutical outlet they work for. However, not many scientific studies have been done to assess the skills and services of the practitioners in the pharmaceutical sector and their contribution to public health (Duwiejua et al 2004, Smith 2009b).

3 MALARIA AS A PUBLIC HEALTH PROBLEM

Malaria is a potentially deadly parasitic disease of global public health relevance, caused by protozoan of the genus *Plasmodium*. Five species of the parasite are known to cause human infection, and these are *P ovale, P malariae, P vivax and P falciparum and P knowlesi.* So far, the most virulent of the parasites is *P falciparum,* which also accounts for the majority of severe illnesses, complications and deaths from malaria. *Falciparum* malaria is also the most prevalent in sub-Saharan Africa, where the disease burden is highest globally (Winstanley et al 2004, Grabowsky 2008, WHO 2008). Malaria is known to exert huge negative impact on population health and economic development in countries where the disease is endemic (Sachs et al 2002, WHO 2008). Over the years, significant efforts have been made both at country level and internationally to reduce the burden of malaria disease and its impact on global health (Coll-Seck 2008). However, whereas significant improvement has been made in Latin America and Southern Africa to eliminate malaria, the disease burden is known to be still high in many areas in sub-Saharan Africa, including Ghana (Feacham et al 2009).

3.1 Life cycle of malaria infection

Malaria is transmitted to humans through the bite of an infected female *anophiline* mosquito (the intermediate host). When drawing blood for egg production, the infected mosquito introduces sporozoites (mature forms of the parasite developing in mosquito) into the blood stream of the human host. On reaching humans, the sporozoites rapidly enter the liver cells where they develop and replicate into merozoites, the parasitic stage that invades red blood cells (RBC) and causes pathology and symptoms of the disease (Guerra et al 2008, NIAD 2008). With respect to *P vivax* and *P ovale* infections, some of the liver forms of the parasite ("hypnozoites") could remain dormant and reactivate later to cause the disease, several months or years after an infective bite from a mosquito (Figure 2).

The factors that determine the extent and intensity of malaria transmission are known to include those that influence the life cycle or development of the parasite in the

mosquito vector and also in humans. These include the warm climatic conditions that promote breeding of mosquitoes, the immune status of the human host, availability of resources to fight the disease and efficient implementation of proven effective interventions for malaria control (Winstaley et al 2004, Snow et al 2005). The incubation period, which is the time between infective mosquito bites to observation of symptoms in the human host, varies from 7 to 30 days. Shorter incubation periods are observed frequently with *P. falciparum* and longer periods with *P. malariae*. In some rare cases, malaria parasites could also be transmitted from human to human through blood transfusion or from an infected pregnant mother to the unborn child (congenital malaria) (Gilles 1998, Winstanley et al 2004).

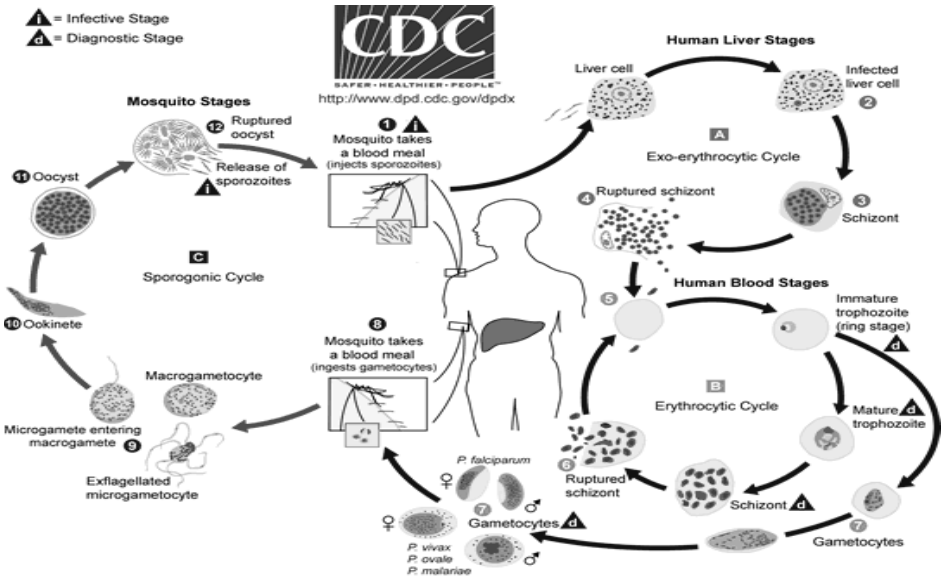

Figure 2. The Life cycle of the malaria parasites (Source-http//www.cdc.gov/Malaria/biology/life_cyclehtm).

3.2 Symptoms of malaria

Individuals with malaria parasites in their blood may develop a range of symptoms, following the breakdown of infected red cells to release merozoites, cell debris, toxins and inflammatory mediators (cytokines) into systemic circulation (Giles 1998, Winstanley et al 2004). The symptoms manifestation may vary from no apparent illness (asymptomatic) to mild symptoms such as: headache, fever, chills, nausea, vomiting, muscle pains and sometimes diarrhea; to severe illness, anaemia and other complications, if no appropriate therapeutic intervention is delivered promptly before the manifestation of the signs of complications (Winstanley et al 2004). Individuals that may be at risk of experiencing rapid progression of symptoms to complications and possibly death include children under five years, pregnant women, HIV and cancer patients, and non-immune travelers from malaria free countries (Sach et al 2002, NIAID 2008). There is also evidence that infants that are born to mothers with malaria infection, frequently records low birth weights; which is believed to be the single most important risk for infant mortality during the first few months of life (Trampuz et al 2003, Winstanley et al 2004). However, individuals resident in stable transmission areas and especially young adults may be infected frequently with malaria parasites, but their illness may be less severe or even asymptomatic due to acquired immunity over years of exposure to the parasites (Snow et al 2005).

There are concerns that the practice to detect malaria illness at home or in primary care facilities with symptoms only without laboratory or other suitable confirmatory assessments may be inaccurate, and possibly lead to unnecessary exposure to anti-malarials or misdiagnosis of other life threatening infections by bacteria or viruses that may present with symptoms similar to malaria (Chandler et al 2008, Sansom 2009). Research is therefore needed to improve the specificity of the process of detection of malaria at home or in primary care facilities in order to optimize community-based initiatives for malaria control.

3.3 Global burden of malaria and malaria in sub-Saharan Africa

Reports from WHO and the global partnership against malaria suggest that 109 countries around the world with estimated 3.3 billion inhabitants are at some risk of having malaria. Over a third of the population at risk (1.2 billion people, which is approximately 40% of the world population) is estimated to live in high transmission areas, where there is more than 1 reported case of malaria per 1000 inhabitants annually (RBM 2008). Individuals that are estimated to be living in high transmission areas include about 50% of populations in sub-Saharan Africa and also 37% of those in South East Asia regions. The remaining 2.1 billion people at some risk of malarial disease live in areas tagged as unstable transmission zones or low risk areas. In these areas, less than 1 reported case of malaria is recorded per 1000 inhabitants annually (Olumese 2005, WHO 2008). The region in the world that has the highest number of inhabitants living in high risk areas or stable transmission zones is sub-Saharan Africa (Figure 3). These high transmission zones also records the highest number of deaths and disabilities from malaria, followed by South-East Asia (Olumese 2005, Snow et al 2005). In Western Europe, North America and Australia, malaria has been completely eradicated since the 1950´s due to effective surveillance networks, increased political will and effective implementation of aggressive evidence-based policies to control the disease (Griffith et al 2007).

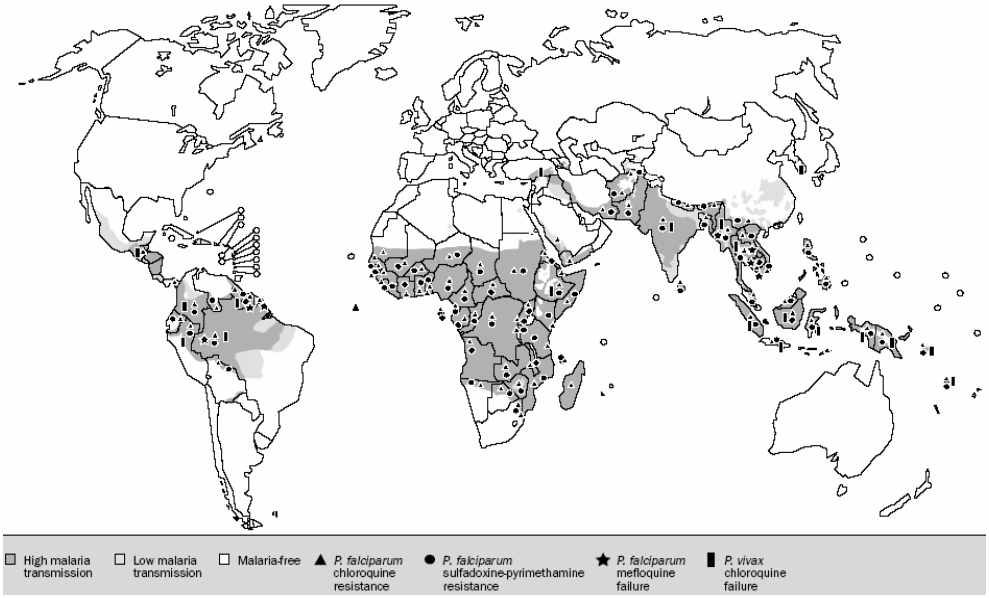

Figure 3. The geographic distribution of malaria risks areas in the world
Source: WHO, World Malaria Report 2008.

3.4 Impact of malaria on well being and socio-economic development

Globally, there is estimated 300-500 million cases of malaria reported each year, resulting in about one million deaths (Snow et al 2005, Grabowsky 2008). About 90% of the deaths from malaria has been found to occur among young children in sub-Saharan Africa. The deaths and disabilities from malaria are also reported to be high among the poor and people in the rural and remote that has less access to preventive and curative interventions for malaria control (Butlet 2004, Winstanley et al 2004, WHO 2008).

Apart from the negative impact of malaria on the health of individuals in endemic countries, malaria is also known to impact hugely on socio-economic and human capital development (Sachs et al 2002, Coll-Seck 2008). In the 1990's, a study that compared the incomes of individuals in malarious and non-malarious countries revealed that, the average GDP of the malarious countries were more than fivefold lower than the countries that were without intensive malaria transmission (Sachs et al 2002, The World

Bank 2007). Currently, malaria is estimated to account for about $12 billion in economic losses each year in sub-Saharan Africa, and also slows the GDP growth of endemic countries by 1.3% per year (The World Bank 2007).

In areas where malaria transmission is intense, chronic infections of children less than five years of age, and other individuals with low immunity is known to result in a complex set of biological and behavioral responses that may have long-term effect on cognitive and mental development (Trampuz et al 2003, Winstanley et al 2004, Eckstein-Ludwig 2009). Also there is evidence that chronic subclinical infections in individuals with low immunity could render them anaemic and malnourished. In addition, continuous subclinical infections with malaria could influence the severity and outcome of other infectious and parasitic diseases, due to weakening of the body's immune mechanisms by the infections (Winstanley et al 2004, Maier et al 2008). In economic terms, it is believed that the direct costs of prevention and treatment of malaria could eat significantly into the disposable income of poor families, in addition to the costs of lost productivity. Large scale dissemination of proven effective public health interventions for malaria control with appropriate education and community participation may therefore lead to improved health and accelerated development in those poor societies in sub-Saharan Africa (WHO 2004, Coll-Seck 2008).

3.5 Global strategies for prevention and control of malaria

Malaria is curable and can also be effectively controlled with the application of appropriate preventive and therapeutic strategies to deal with the disease transmission process and parasites development in humans (Morel et al 2005, Feacham et al 2009). In 1998, a global partnership under the leadership of WHO, was established to intensify international and country-based efforts to reduce the burden of malaria and its toll on human lives and economic development. The partnership launched an initiative called "Roll Back Malaria (RBM)" to drastically reduce morbidity and mortality from malaria by 2010 and 2015 (WHO 2004, Coll-Seck 2008, WHO 2008).

The targets set to be achieved by the RBM initiative were that:

- by 2010, 80% of people at risk of malaria are protected from infective mosquito bites
- 80% of malaria patients are promptly diagnosed and treated within appropriate medicines within 24 hours of onset of symptoms
- the morbidity and mortality from malaria should be reduced by 50% compared to the situation in 2000.

The milestones for 2015 are that, morbidity and mortality from malaria should be reduced by 75% in comparison with the situation 2005. The institutions and countries that formed part of the roll back partnership include: WHO, UNICEF, World Bank and a consortium of donors, the malaria-endemic countries, researchers, policy-makers and private sector enterprises.

The strategies to be used to achieve the RBM targets include: 1) Early case detection or diagnosis of malaria, followed by immediate therapeutic action with effective antimalarials 2) Integrated vector control, using indoor residual spraying (IRS) and efficient management of the environment to interrupt with the breeding of the insect vector, and also using insecticide treated bed nets (ITN) and in particular long-lasting insecticide nets (LLINs) to protect all individuals at risk of malaria infection. In case of limited resources, the priority is to protect children under five years and pregnant women 3) Intermittent preventive therapy approach against malaria in pregnancy (IPT) with 2 or 3 doses of an effective chemo-prophylactic agent in the second and third trimesters of pregnancy in high transmission areas 4) Prevention and control of malaria epidemics through disease surveillance, monitoring and evaluation of intervention strategies to assess impact. 5) Operation research to generate evidence to guide policy recommendations to support malaria control activities in disease endemic countries. A review by Webster and colleagues on delivery systems for intervention strategies to reduce child mortality in sub-Saharan Africa revealed that there are still problems with equity of coverage and dissemination of proven effective interventions for malaria control (Webster et al 2005). However, in Eastern African countries like Rwanda,

Ethiopia and Zambia, where there has been co-ordinated efforts to implement and roll out these interventions in large scale. There has been reports of increased access and utilisation, causing malaria cases to drop by more than 50% (Coll-Seck 2008, WHO 2008).

3.6 Malaria control in Ghana and the role of medicine outlet practitioners

Malaria contributes significantly to ill health as well as infant and maternal deaths in Ghana (Agyepong et al 2004, Koram et al 2005, Malaria Operational Plan FY-08). Malaria is known to account for about 40-50% of outpatient consultations in hospitals and clinics, and also contributes directly to low productivity, reduced school attendance and poor academic performance among school children in Ghana (Guerin et al 2002, Goodman et al 2007a). A recent report from MoH suggests that malaria still accounts for close to 60% of under-five hospital admissions, 8% of hospital admissions in pregnant women and 7% of disability adjusted life years lost (Malaria Operational Plan FY-08).

Since the late 1990's, Ghana has committed itself to the global partnership for malaria control. Ghana is also a signatory to the Abuja declaration for malaria control and sustainable development in Africa, and also a beneficiary of the US President's initiative against malaria in sub-Saharan Africa. The initiatives for malaria control in Ghana are in line with the global strategies, but adapted to suit country needs, based on the available resources and local patterns of parasite resistance to existing anti-malarials (WHO 2004, Koram et al 2008). These include: 1) improvements in environmental sanitation, the use of preventive interventions like indoor residual spraying and insecticide treated bed nets (ITN) to avoid human contacts with mosquitoes 2) administering IPT with adequate doses of sulfadoxine/pyrimethamine (S/P) to prevent malaria illness in pregnancy and 3) promptly diagnosing and effectively managing uncomplicated malaria with adequate doses of artemisinin-based combination products. With regards to severe malaria and malaria infection in pregnancy, the policy initiative recommends immediate referral to the appropriate institutions with the best competence for disease management and patient care, once they are identified promptly at home or in the community.

In Ghana, legal sources of medicines and other commodities for malaria control are hospitals/clinics, community pharmacies and licensed chemical shops. Studies on health seeking behaviour among Ghanaians suggested that, community pharmacies and licensed chemical shops were usually the first port of call for health advice and treatment for many individuals with symptoms suggestive of malaria (Smith 2004, van den Boom et al 2004, Goodman et al 2007a). The explanation given for this observation was that, those community-based retail outlets operated for long hours, were not charging consultation fees, and patrons did not have to wait for long hours before having access to practitioners to purchase anti-malarials. The retail practitioners were also perceived to be friendlier, and payments for anti-malaria services were flexible for known community members (Ahorlu et al 1997, Goodman et al 2007a, Smith 2009b).

In general, medicine outlets whether in hospitals, clinics or community-based retail outlets are usually the last point of encounter with patients before they take their anti-malarial medications. Policy makers and other health stake holders have therefore identified the medicine outlets as important units in the health system, where appropriate intervention programs could be initiated to promote access to sound public health interventions for malaria control (GNDP 2004, WHO 2004). However, not much scientific information is available on operations in medicine outlets in Ghana, and the safety of services rendered for malaria control.

4 AIMS AND OBJECTIVES OF THE STUDY

The aim of this study was to evaluate the pharmaceutical settings and primary care practices for malaria control in medicine outlets of both public and private sector facilities, and to assess whether the practices conformed to current global and national policy initiatives for malaria control. The secondary aim was to identify specific areas in practice to where appropriate interventions could be targeted to improve the safety of services in the pharmaceutical sector for malaria control.

The specific objectives were:

i) to assess self care and health facilities-based management of malaria, and the possible role played by medicine outlet practitioners in ensuring the appropriateness of use of the anti-malarials.

ii) to apply existing standard indicators to assess the infrastructure, practice settings and commodities other than drugs, that are stocked for malaria control in licensed medicine outlets.

iii) to assess the availability and supply of anti-malarial medicines in the outlets and how it conformed to national policy recommendations for malaria therapy.

iv) to assess the human resources available in the outlets, their knowledge on current initiatives for malaria control, and their practices for prevention and management of malaria.

5 MATERIALS AND METHODS

5.1 Context of the study

Due to the limited number of formal health care institutions in the Ghanaian health system, the contribution of medicine outlets, and in particular those in the retail sector to malaria control, may be of strategic importance to public health, if the staff in the outlets deliver their services according to evidence-based guidelines for best practices.

In the retail sector outlets, the expected services for malaria control include educating the public to create awareness about malarial disease and advising clients on behaviours and practices for malaria prevention. Other services may be identifying malaria infections, stocking and supplying appropriate medicines for malaria therapy, and counselling clients on the use of the anti-malarials and other commodities purchased for prevention and therapeutic management of malaria.

In the hospitals and clinics, the malaria control services may include procurement of medicines and other commodities for malaria control, and ensuring its proper storage and stocking on shelves. Other services may be re-distribution of anti-malarials to out-patient and/or in-patient sub-outlets, where they are re-packaged and dispensed for prevention and treatment of malaria. In the major hospitals, the medicine outlets staff may consult with clinician's to ensure the appropriate selection and supply of medicines for malaria therapy. In the clinics and primary care centres, anti-malarial supply and other services for malaria control may be performed by nurses or some other staff who may not have pharmaceutical background, but who has been trained on the job within the facilities. Staff members in medicine outlets may also advise patients on appropriate practices to prevent further malaria infections.

As part of initiatives to improve practices for malaria control in medicine outlets, MSH and public institutions like Ghana Health Service (GHS), National Malaria Control Program (NMCP) and Pharmacy Council, have been organizing training programs for medicine outlets practitioners and other employees in the pharmaceutical sector. The MSH has been working with Pharmacy Council to improve malaria control practices in the retail outlets, whilst GHS and NMCP have been targeting the medicine

outlets of hospitals and clinics to improve practices. However, not much is known about the effectiveness of these interventions on the capacity of medicine outlets staff to manage pharmaceuticals and practice safely for prevention and management of malaria.

5.2 Overview of methods used and study design

This research is based on two field studies that were conducted in the years 2002 and 2007 respectively. The first part was an anti-malarial utilisation study that involved patients attending rural and urban based health care facilities in Southern Ghana for malaria therapy. The design was prospective and non-experimental, and it involved both new ambulatory and admitted malaria patients that visited the two facilities in April and May 2002. The second part was designed, based on the results of the first study; and this was an indicator-based assessment of the settings and practices for malaria control in the licensed medicine outlets. The design was cross-sectional, and it involved medicine outlets selected from hospitals/clinics, community pharmacies and licensed chemical shops in urban and rural areas in two regions in Northern and Southern Ghana. Both studies were conducted during high rainfall seasons and peak periods of malaria transmission in Ghana.

Table 1. Summary of methods used in studies I–IV.

Study	Objective	Brief description of the study & participants	Methods	Analysis
I	To assess the appropriateness of self care and health facilities-based management of malaria, and role played by medicine outlets	A Prospective observational study involving patients diagnosed with malaria in Agogo hospital and Suntreso Polyclinic n=500	Patient/carer interviews and review of clinical notes to assess the quality of use of anti-malarials for self care/health facilities-based management	Descriptive statistics Comparison of the % of inappropriate use of anti-malarials for self-care, in relation to the source of medicines.
II	To assess the availability and supply of anti-malarials in the medicine outlets, and its conformity to national recommendations	A cross sectional study of community pharmacies n=35; hospitals/clinics n=31 and Licensed chemical shops n=64 from urban and rural areas in Northern and Southern Ghana Interview of the most senior practitioner n=130	Combination of methods including interviews, observation of staff practices and review of documents such as prescriptions and drug invoices	Descriptive statistics $\chi 2$ analysis to assess the differences in availability of anti-malarials in the outlets and the level of adherence to policy recommendations
III	To assess the human resources available, their knowledge of current initiatives for malaria control and their practices for malaria control.	Same outlets as above Persons interviewed and observed: the practitioner in-charge n=121 and others recommended by staff-in charge of the outlet at the time of data collection n=33	Combination of methods such as structured interviews, observation of practice skills of staff and review of prescriptions/clinical notes.	Descriptive statistics. Rating of the practitioners knowledge and practice skills in the different outlets, according to professional status.
IV	To assess the quality of infrastructure and settings in the medicine outlets for the prevention, treatment and control of malaria in Ghana	Same outlets as above Personnel interviewed: Shop owners or senior personnel in-charge of outlets at the time of data collection n=130	Inspection/observation of practice settings to assess infrastructure, products & services for malaria control, review of documents and staff interviews when necessary	Descriptive statistics $\chi 2$ analysis to assess the differences between the different outlets regarding the infrastructure and practice settings Rating of outlets based on the structures and suitability of the practice settings

5.3 Self care and health facilities-based management of malaria (I)

5.3.1 Study setting and participants

This study involved a cohort of patients that were diagnosed parasitologically (63%) and/or clinically (37%) with malaria at a 240 bed Presbyterian hospital in rural Ashanti (Agogo) and a Polyclinic in Kumasi, the largest city in Ashanti region, in Southern Ghana. Three hundred of the patients were recruited from Agogo hospital and 200 from the polyclinic in Kumasi. The study participants were recruited daily among patients that visited the two facilities between 1st of April and 15th of May in 2002. The patients were recruited consecutively from every other newly diagnosed case of malaria at the out-patient units of the facilities. In addition, all patients admitted and detained for malaria therapy within the study period were also included.

5.3.2 Data collection and analysis

Data were obtained on patients' demographics, previous episodes of malaria two weeks prior to health facility attendance, the medicines used for treating the previous malaria episode and its appropriateness in terms of dosage, frequency, and duration of use. These data on the anti-malaria medication history prior to hospital attendance and its use, was to enable the assessment of the appropriateness of self-care for malaria therapy. Data was also obtained on the medicines used for malaria therapy in the health facilities and their therapeutic outcomes. On the patients that had self-medicated two weeks prior to health facility attendance, the sources of the anti-malarials were noted. The sources of the medicines for self-care included community-based retail outlets, neighboring clinics, and left over medicines at home, that were obtained from the retail outlets or hospitals and clinics.

The methods utilized for data collection included patient interviews, for those that were 12 years of age and above or through carer interviews for those that were less than 12 years. The data collection instrument was a structured questionnaire. Where necessary, pill identification and anti-malarial medicines package assessments were

used to validate the information obtained from the interviews, on the use of anti-malarials at home or in the health facilities. Other sources from where data was obtained to validate the information from the interviews included the patient's prescription cards and clinical notes. These records were reviewed to document the anti-malarials that were prescribed for the patients on admission, or those detained for further observation in the health facilities. The appropriateness of use of the anti-malarials for both self-care and health facilities-based therapy of malaria was assessed using the national treatment guidelines that was available in 2002.

The data obtained was coded, stored, and analyzed using SPSS for Windows Version 11. Procedures included frequencies and percentages on patient demographics and the quality of use of anti-malarials, both for self-care and in the health facilities. The percentage of inappropriate use of the anti-malarials for self care prior to health facility attendance together with the 95% CI was computed and compared in order to assess the differences between the sources from where the medicines were obtained for self-care and its relation to inappropriateness of use. With regards to the therapeutic outcomes assessment in the health facilities, the outcome measures used included clinical cure, defined as rapid resolution of symptoms, coupled with improved well being of the patients, 3 days after initiation of malaria therapy; and treatment failure was defined as worsening of symptoms or death from malaria 24 hours after initiation of therapy.

5.4 Assessment of the pharmaceutical settings and practices for malaria control (II–IV)

These medicine outlets involved were selected from urban and rural areas in Ashanti region in Southern Ghana, and Northern region in Northern Ghana. The urban outlets were sampled from the largest cities (Kumasi and Tamale) in Ashanti and Northern regions respectively. The rural outlets were selected from the districts neighboring Kumasi and Tamale. The two diverse study areas were chosen for the following reasons: The Ashanti region is more industrialised, and is also one of the regions with the highest concentration of pharmacies, pharmacists and health care facilities. The Northern region on the other hand is the largest in terms of size in square kilometres,

but it is among the poorest in Ghana in socio-economic terms, and has fewer numbers of health care facilities and health care professionals. People in the Northern region mostly access health services through licensed chemical shops and traditional medicine practitioners. The two regions were also selected because the few evaluation studies on the pharmaceutical sector that has been done in Ghana, has involved regions that are closer to the capital, such as the Greater Accra, Eastern and others like Volta and Central, which are along the West coast of Africa (Figure 4).

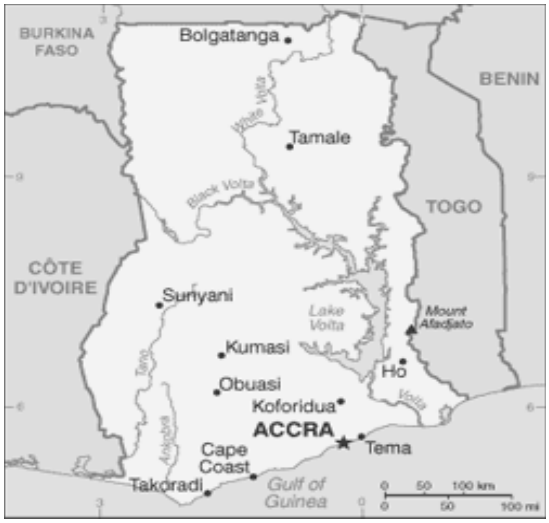

Figure 4. Map of Ghana, showing major cities and municipalities.

5.4.1 Sampling of facilities

The number of medicine outlets that constituted the sampling frame for studies II to IV, was based on the records of hospitals/clinics, community pharmacies and licensed chemical shops, that are maintained by Ghana Health Services (GHS) and Pharmacy Council respectively, at the study areas at the time of data collection (May to July 2006). Because of the inequalities in the distribution of medicine outlets in the two selected regions, a sampling strategy was adopted to ensure the inclusion of sufficient numbers of each of the different types of medicine outlets in the two regions, and also in

both the urban and rural areas. The community pharmacies and licensed chemical shops were selected from the list of gazette outlets obtained from Pharmacy Council. The hospitals and clinics were selected from the list of gazetted institutions obtained from GHS.

Due to the low number of health care facilities in the rural areas, all the hospitals and clinics located in the rural areas were included in the sample (Figure 5). All chemical shops situated on the main roads leading to hospitals and clinics in the rural areas were also included because of the ease of accessibility. There were no community pharmacies in the rural areas of either region. Similarly in the city of Tamale, because of the low numbers, all the community pharmacies and hospitals and clinics were targeted for inclusion in the study (1 clinic declined consent). Of 321 chemical shops in Tamale, 35 were randomly selected across the city, and they all consented for participation in the study. In Kumasi, where the facilities were many, a random sampling procedure was used to select the outlets across the length and breadth of the city. These included 25 community pharmacies, 13 hospitals and clinics, and 17 licensed chemical shops, none declined consent. Thus the final sample consisted of 130 facilities comprising 64 licensed chemical shops, 35 community pharmacies, and 31 hospitals and clinics (Figure 5).

Informed consent: A consent form that explained the purpose of the study was sent to all the heads of hospitals/clinics and to the owners of the pharmacies and licensed chemical shops, asking for their consent to take part in the study. Data collection only preceded once the heads of the healthcare facilities and the pharmacy administrators or owners of the licensed chemical shops gave their consent. Approval to commence the study was also sought from GHS and Pharmacy Council, who have direct regulatory and oversight responsibilities over the medicine outlets in the public health sector and those in the private sector respectively.

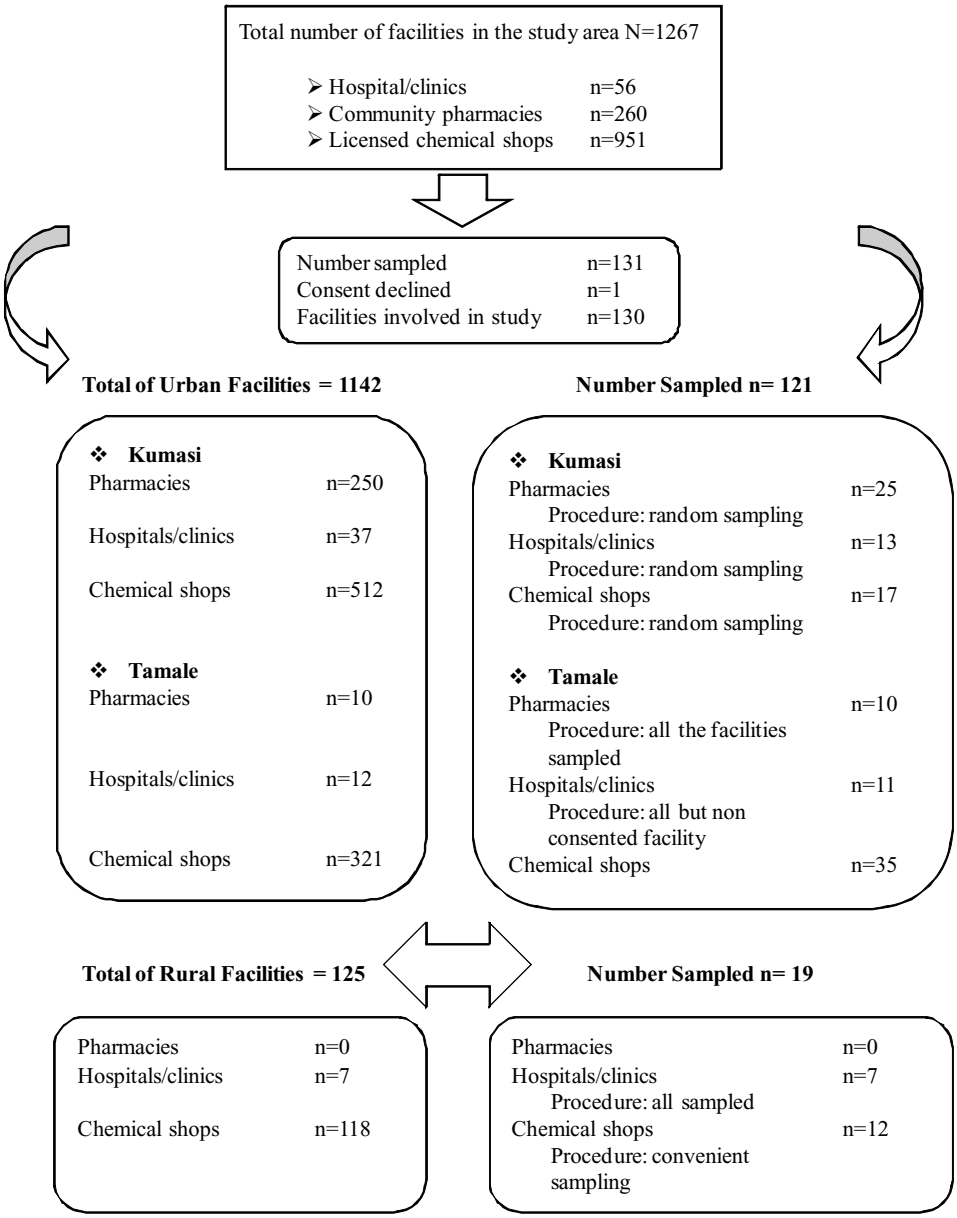

Figure 5. Medicine outlets available in the study area and methods used in sampling.

5.4.2 Indicators for assessments of the pharmaceutical settings and malaria control practices

Different sets of indicators were used to assess the infrastructure, practice settings, anti-malarial products as well as commodities stocked for mosquito control, the available human resources, their knowledge, skill and practices for the prevention and management of malaria (Appendices II & IV). The indicators used for assessing the infrastructure and the pharmaceutical settings were based on national practice standards for pharmaceutical services in Ghana, and good pharmacy practice guidelines for developing countries by FIP. The indicators used for assessing the availability, selection and supply of medicines for malaria therapy and IPTp; and also the human resources, their knowledge, skill and practices for malaria control, were based on the national policy initiative and practice guidelines for malaria control, the standard operating procedures for pharmaceutical services by GHS and the WHO-led RBM initiatives (Table 2).

5.5 Data collection (II–IV)

5.5.1 Infrastructure and settings for pharmaceutical services

The relevant data on the infrastructure and the settings for pharmaceutical services was obtained, to enable the assessments of the adequacies of lightening, space, ventilation, and temperature conditions in the outlets. As part of the assessments, data was also obtained on cleanliness and hygiene within the premises, suitability of dispensing and diagnostic tools, the stocks and appropriateness of storage conditions for the anti-malarials and other commodities stocked for prevention and management of malaria. In addition, data was obtained on the availability of reference materials in the outlets and its usefulness for malaria therapy. Again the type of records maintained in the outlets and how they were stored (i.e. whether in files, computer etc) was also noted. Finally, the status of the outlet as a service provider for National Health Insurance Scheme (NHIS) was also noted. NHIS accreditation is based on satisfying the same

quality criteria for pharmacies and chemical shops to be considered for registration by Pharmacy Council.

The data on lightening, space, ventilation, humidity and temperature conditions in the outlets were obtained by inspection/observation of the pharmaceutical settings and ticking the appropriate indicator on the check list prepared from the appropriate standard documents (Table 2). Data on cleanliness and hygiene were also obtained by inspecting/observing the shelves, dispensing tools, working environment, products on the shelves to assess whether they were free from dust or cobwebs. The availability of bins and how the waste generated in the premises was disposed of was also enquired from the staff-in charge of the outlets at the time of data collection. In addition the suitability of the packaging materials (i.e. paper/plastic envelopes, the original container/packaging material for anti-malarial suspensions), the availability of refrigerator for anti-malarial suppositories, computer and/or files or cabinets for storing patients data on medications, drug sale records/invoices or NHIS records was sought for by inspection/observation or through interview of the staff in-charge.

5.5.2 Availability and supply of medicines for chemotherapy and malaria prevention in pregnancy (IPTp)

This section involved the assessment of the types of anti-malarials stocked in the medicine outlets and supplied to the public for malaria therapy. The data collected enabled the assessments of the medicines available in the outlets and supplied for malaria therapy, and whether it conformed to the policy recommendations and guidelines for malaria therapy in Ghana. The data obtained included, the specific type of outlet under investigation, its geographic location, the anti-malarial products available in stock, as well as the range of products and their registration status with FDB.

The methods used for data collection included face-to-face interviews, direct observation of staff's practices and the review of the patient's anti-malarial medication records (i.e prescriptions/folders) and other documents on procurement/sourcing of the anti-malarials. Information regarding the products available in stock and the sources

from which they were obtained was extracted from the staff in-charge of the outlet through structured interviews. Observations were then made to check the types of anti-malarials available in stock, and the services of the dispensing staff when packaging, labeling and supplying medicines to patients/clients for malaria therapy. The prescriptions/clinical notes of patients, store receipt vouchers and drug sale invoices in the outlets were also reviewed to ascertain the medicines selection and sources of the medicines supplied for malaria therapy, as well as the level of adherence to policy recommendations and guidelines for malaria therapy. These combined methodological approaches adopted enabled the collection of adequate data for the assessments, and also validation of the data gathered through the interviews and the observation of malaria control practices.

5.5.3 Human resources in the outlets, their knowledge, skills and practices for malaria control

In this section, data was obtained on the available human resources and their status as professional or non professional health or pharmaceutical service providers. Data was also obtained about the knowledge of the staff-in charge of the outlets, or other frontline personnel on: malarial disease transmission, the main sign and symptoms of the disease, initiatives for malaria control and the medicines recommended for uncomplicated malaria case management, as well as IPTp. The data for knowledge assessment was obtained through structured interviews, where the interviewers asked the exact same questions consistently to all the respondents. The staff's skill and practices for malaria disease prevention were assessed by observing their interaction with clients, and the advice given to avoid contacts with mosquitoes that transmit the disease and checking against the standard indicators (Appendices III & IV).

In the retail outlets, staff's practice skills to identify the signs and symptoms of malaria and the medicines selected and/or supplied for malaria therapy and how the dosage instructions were communicated to clients, were assessed using the indicators derived from the RBM and national policy recommendations and guidelines for malaria therapy (Table 2). In the hospitals/clinics, the health promotion and disease prevention

practices were also assessed by observing the counseling of the medicine outlets staff to patients on environmental sanitation, the use of mosquito repellants and ITNs to avoid further malaria infections. The quality of the malaria therapeutic practices were assessed by linking the their depth of knowledge about the medicines recommended for malaria therapy with the medicines selected and/or supplied for malaria therapy, and how they communicated the dosage instructions to the patients. The medicine outlet staff from whom data were obtained was the outlets owners in case of the licensed chemical shops, or the staff-in charge of the outlets at the time of data collection, plus any other practitioner recommended by the staff-in charge. In the outlets with more than two practitioners of different professional status, each of the cadres of practitioners available was selected to be observed and interviewed for data. On the knowledge, skills and practices assessments, 9 of the 130 medicine outlets originally sampled for the study (including 8 licensed chemical shops and one clinic), were not included in data collection, leaving 121 outlets. The reason for exclusion of those outlets for data collection was that, they did not have any free staff available to be interviewed or observed.

Table 2. Indicators for pharmaceutical settings, knowledge assessment and malaria control practices.

Subject of evaluation	Materials used for the Indicators	Indicators and data sets measured
Settings for pharmaceutical services	National Practice Standards for Pharmacies and Chemical Shops Good Pharmacy Practice Standards for Developing Countries by FIP	- Space, lighting, ventilation - Clean and Hygienic environment - Diagnostic and dispensing tools - Privacy during counselling - Storage conditions, including that for products requiring cold storage - Reference materials - NHIS records/accreditation status
Availability and supply of anti-malarials and other commodities for prevention and control of malaria	RBM Document and Malaria Control Policy of Ghana.	- Availability of anti-malarials, insecticide bed nets and mosquito repellents - Range of anti-malarials/other commoditie in stock - Sources of anti-malarials/other commodities - Registration status with FDB - Packaging of products - Physical appearance and product expiry date
The human resources available, their knowledge, skill and practices for prevention and control of malaria	National Practice Standards for Pharmacies and licensed Chemical Shops Standard Operating Procedures for Pharmaceutical Services in Hospitals/Clinics RBM document and Malaria Control Policy, and national treatment guidelines	**Human resource & training** - Professional status of the personnel providing anti-malarial service - Educational background - Training obtained for malaria control and trainer **Disease prevention practices** - Advise on environmental management & mosquito vector control - Use of repellents and insecticide treated nets **Malaria therapeutic practices** - Anti-malarials selected - Dosage estimation - Labelling of anti-malarials - Information on how to use **Knowledge Assessment** - Disease transmission - RBM and national strategies for malaria control - The medicine used for IPT in pregnancy, no of doses and period of IPT administration **Skills assessment** - Content of advice for malaria prevention and mode of delivery - Recognition of symptoms for uncomplicated malaria - Recognition of symptoms for complicated malaria and action taken - Counselling information on use of ACTs and mode of delivery

Table 3. Current national policy recommendations/guidelines for malaria case management and IPTp in Ghana .

Nature of malaria case/therapy	First line recommendation	Alternative therapy
Uncomplicated malaria	Oral artesunate/amodiaquine	Oral artemether/lumefanthrine
Complicated malaria	Parenteral quinine initially and therapy switched to oral dosage forms when patients are conscious and able to take oral medications	Parenteral artemether or rectal artesunate,
IPTp	Oral sulfadoxine/ pyrimethamine	In case of breakthrough malaria infection, Quinine or artmisinin combination therapy (ACT) is recommended

All dosages for medications of malaria case managent and IPTp are to be determined according to patient's weight in mg/kg body weight

5.6 Coding of data and data analysis

Coding frames were devised for all data obtained in studies II to IV, verified by the main academic study advisor and the data coded appropriately. The coded data was then entered into SPSS (version 14; SPSS, Cary, NC) for analysis. The procedures used for data analysis included frequencies and percentages to describe the characteristics of the different types of pharmaceutical settings, the products stocked, staff resources, their knowledge, skill and practices for malaria control, and whether they adhered to policy recommendations in selecting medicines for the management of malaria.

On the suitability of infrastructure and the settings for pharmaceutical/malaria control services, the outlets were rated as poor, acceptable and good. The rating was based on the number of outlets that met the standards/criteria used for the assessments (Appendix II & III-Check list/indicators).

i) Facilities that met less than 40% of the requirements of the practice standards were rated as poor.

ii) Those that met between 40 -75% were rated acceptable

iii)Those that met more than 75% of the standards were rated as good.

On the availability and supply of medicines for malaria control, the level of adherence to policy recommendations in the respective outlets, when selecting and/or supplying medicines for malaria therapy was classified as:

i) Strict adherence: - when the anti-malarials supplied for drug therapy were restricted exclusively to those recommended in the national policy for malaria therapy.

ii) Partial adherence: - when the anti-malarials chosen and supplied for malaria therapy sometimes, but not always, conformed to national policy recommendations

iii) Non adherence:- when the choice and supply of anti-malarials did not follow the recommendations of the national policy.

Chi-square analysis was used to compare the differences in availability of anti-malarials between the different medicine outlets and their level of adherence to policy recommendations, during the selection and supply of anti-malarials to patients/clients.

The medicine outlets staff's knowledge, skill and practices for malaria control were rated as low, intermediate or high, depending on their depth of knowledge on current initiatives for malaria control and the practices demonstrated for prevention and control of malaria.

i) The practitioners with low ratings on knowledge, skills and practices were those who were only knowledgeable about the mode of malaria transmission, had little or no knowledge about current initiatives for malaria control in Ghana, neither did they have the skill to recognize malaria cases and to manage it.

ii) The practitioners with intermediate ratings were those that demonstrated skills to recognize malaria cases and could counsel clients on practices for disease prevention, but had deficiencies in knowledge about current initiatives for malaria control, including IPTp and the skills to manage malaria cases appropriately.

iii) Practitioners that demonstrated the requisite depth of knowledge on current initiatives for malaria control including IPTp and the skills for efficient case management of malaria was rated high.

6 RESULTS

6.1 Self-care and health facilities-based management of malaria (I)

Of the 500 patients recruited in this study, 17% were diagnosed as cases of severe malaria, 8% were cases of moderate to severe malaria and 75% were uncomplicated malaria. Eighty nine percent of the severe malaria patients were children under five years of age (Table 4).

Table 4. Severity of malaria according to age of the patients.

Severity of malaria	Patients aged 5 years or below n (%)	Patients aged 6 years and above n (%)	Total n (%)
Uncomplicated	211 (56)	166 (44)	377 (75)
Moderate to severe	29 (76)	9 (24)	38 (8)
Severe	76 (89)	9 (11)	85 (17)
Total	316 (63)	184 (37)	500 (100)

6.1.1 Self-care for malaria and appropriateness of use of anti-malarials

Forty three percent of the patients had undertaken self medication for malaria therapy two weeks prior to health facility attendance. Of these 76% had taken chloroquine, 9% took S/P, another 9% took herbal preparations and 6% took amodiaquine. About 50% of the patients obtained the medicines for self care from licensed chemical shops, 21% obtained their medicines from community pharmacies, 9% from neighbouring hospitals/clinics and the remaining 20% used left over medicines obtained from community-based retail outlets or neighbouring hospitals/clinics.

Altogether, 77% of the patients used incorrect dosage or did not complete the course of the anti-malarials obtained for self medication. In relation to the sources of the medicines, 95% of those who used left over medicines at home for the self care used the medicines incorrectly. Eighty six percent of those who sourced their medicines from licensed chemical shops used them incorrectly. Fifty four percent of those who sourced

their medicines from community pharmacies used them incorrectly, whilst 37% of those who sourced their medicines from neighbouring hospitals/clinics used the medicines incorrectly. The level of 'incorrect use' of anti-malarials was significantly higher when the medicines were left over anti-malarials obtained at home from friends and relatives or when the medicines were sourced from licensed chemical shops (Table 5).

Table 5. Source of the anti-malarials for self-care, and percentage of the patients that used the medicines incorrectly.

		'Incorrect use' of anti-malarials	
Source of anti-malarials	***N (%)**	****n (%)**	**95% CI**
Left over medicines	42 (20)	40 (95)	88–100
Licensed chemical shop	107 (50)	92 (86)	79–93
Community pharmacy	45 (21)	24 (54)	39–69
Neighbouring clinics	19 (9)	7 (37)	15–59
Total	213 (100)	167 (77)	

*N represents the number of patients/clients who sourced the anti-malarials for self care.
**n represents the number of patients that used the medicines incorrectly.

6.1.2 Malaria therapy at the health facilities and therapeutic outcomes

Of the 500 patients recruited into the study, only 51% including all those admitted or detained for therapy in the facilities, could be followed up for outcomes assessment. The remaining 247 patients could not be traced for outcomes assessment. However, for the patients that could be traced, they were followed daily and their health condition and outcomes to the malaria therapy administered at the facilities assessed. Quinine often in combination with S/P was the preferred medicine for severe malaria at Agogo hospital. Fifty one of the 85 patients diagnosed with severe malaria were managed with quinine at Agogo, achieving a cure rate of 98% and only one death. At the polyclinic in Kumasi, artemisinin derivatives were supplied for the management of severe malaria, achieving a cure rate of 100%. Among the artemisinin derivatives, artesunate was used in 80% of the cases, and the remaining 20% were managed with β artemeter or dihydroartemisin products.

In both health facilities, all the patients detained with moderate to severe malaria were treated with amodiaquine, which achieved a cure rate of 84%. Also of the 130 patients diagnosed as having uncomplicated malaria in both facilities (i.e. those that could be traced for outcomes assessment), these were supplied chloroquine for the disease treatment, which achieved a cure rate of 85%. In both Agogo hospital and the polyclinic in Kumasi, the anti-malarials were changed within 36 to 48 hours to more effective alternatives (parenteral quinine or artemisinins), once the patients were failing to respond to the initial anti-malaria therapy. None of the patients in both health facilities were treated with artemisinin combination products. At the time of data collection, chloroquine was the recommended first line medicine for uncomplicated malaria in the national standard treatment guidelines.

6.2 Assessment of the infrastructure and settings for pharmaceutical services (IV)

Ninety five percent of the medicine outlets (n=124) did satisfy the standard criteria for space and ventilation. More than 70% of the outlets (n=93) had adequate lighting that enabled easy readability of labels, literature etc. The majority were hospitals/clinics and community pharmacies. Forty percent of the licensed chemical shops (n=26) had inadequate lighting conditions (Table 6). With regards to hygiene and privacy in the outlets**,** less than 50% satisfied the standard criteria for hygiene and cleanliness (n=55) and also for assurance of privacy during counselling (n=51). The community pharmacies were relatively more clean (66%) compared to the hospitals/clinics and licensed chemical shops (<36%) ($p<0.01$). They also constituted more than half of the outlets that had a counselling area (n=26).

Table 6. Infrastructure and settings for pharmaceutical services.

	Hospitals/clinics N=31 n (%)	Community pharmacies N=35 n (%)	Licensed chemical shops N=64 n (%)	Total N=130 n (%)
SPACE, VENTILATION & LIGHTENING				
Space and Ventilation	29 (94)	35 (100)	60 (94)	124 (95)
Lighting	25 (81)	30 (86)	38 (59)	93 (72)
HYGYEINE, CLEANLINESS & PRIVACY DURING COUNSELLING				
Availability of bins and proper disposal of waste	31 (100)	35 (100)	58 (91)	124 (95)
Clean and tidy practice environment	11 (35)	23 (66)	21 (33)	55 (42)
Privacy during counselling	13 (42)	26 (74)	12 (19)	51 (39)
TEMPERATURE/STORAGE CONDITIONS FOR PRODUCTS				
Functioning fan	31 (100)	35 (100)	60 (94)	126 (97)
Availability of functioning fridge	23 (74)	31 (88)	14 (22)	68 (52)
Functioning air conditioner	8 (26)	22 (63)	4 (6)	34 (26)
Wall thermother for recording ambient temperature	5 (16)	5 (14)	0 (0)	10 (8)

6.2.1 Diagnostics, dispensing tools and packaging of anti-malarials

More than 90% of the outlets (n=119) used dispensing spoons for counting loose anti-malarial tablets. Twenty five percent (n=33) had a weighing scale for determining the weight of patients or clients. These included 48% of the hospitals/clinics (n=15), 43% of the community pharmacies (n=15) and only 9 chemical shops. Again less than 30% of both retail outlets had clinical thermometer for fever assessment, and none had Rapid Diagnostic kits (RPD) or any other tool to aid malaria diagnosis (Table 7).

With regards to the packaging of anti-malarials, 97% of the outlets (n=126) dispensed anti-malarial suspensions in the manufacturer's original pack. Seventy five percent (n=97) dispensed anti-malarial tablets or capsules including blistered packed products in paper envelopes. The use of paper envelopes were higher in the community pharmacies (80%) and licensed chemical shops (90) compared to the hospital/clinics (32%). Again 48% used air-tight plastic envelopes for bagging loose anti-malaria tablets. The use of plastic envelopes was higher in the hospitals/clinics (77%) compared to the community pharmacies (66%) and licensed chemical shops (16%) Table 7.

Table 7. Instrument/materials for diagnosis, dispensing and packaging of anti-malarials.

	Hospitals/clinics **N=31** n (%)	**Community pharmacies** **N=35** n (%)	**Licensed chemical shops** **N=64** n (%)	**Total** **N=130** n (%)
DISPENSING & DIAGNOSTIC TOOLS				
Dispensing spoons	26 (84)	35 (100)	58 (91)	119 (92)
Dispensing trays/tablet counters	10 (32)	11 (31)	4 (6)	25 (19)
Weighing scale	15 (48)	15 (43)	3 (9)	33 (25)
Clinical thermometer	*N/A	12 (34)	4 (6)	
Rapid diagnostic sticks or alternative diagnostics	*N/A	0	0	
PACKAGING MATERIALS FOR ANTI-MALARIALS BE ING DISPENSED				
Original container for anti-malarial suspensions	31 (100)	35 (100)	60 (94)	126 (97)
Paper envelopes	10 (32)	27 (80)	60 (94)	97 (75)
Plastic envelopes (Airtight)	24 (77)	23 (66)	16 (25)	63 (48)

*N/A represents Non Applicable for the outlet

6.2.2 Medicine outlet records, tools for communication and reference literature

Seventy four percent of the outlets (n= 96) stored prescription and other patient information records in files, folders and in cabinets. These included all the hospitals/clinics and community pharmacies. Only 47% of the chemical shops had files and/or cabinets to keep the available records. Twenty eight percent of the outlets (n=36) had a computer with appropriate software for keeping the records. In relative terms, significant proportion of the community pharmacies (60%) had a computer compared to the hospitals/clinics (29%) and the licensed chemical shops (9%) ($p<0.001$) (Table 8). On NHIS accreditation and the respective records, 77% of the hospitals/clinics were accredited, and kept the appropriate records. However, less than 50% of both retail outlets, with the worst being licensed chemical shops, were not accredited by NHIS as service providers. When interviewed, some of the retail pharmacy owners indicated that they failed to seek accreditation, because of complicated bureaucracies and time consuming processes involved in getting accredited and also receiving reimbursement for services delivered. On tools for communication, 96% of all the medicine outlets (n=125) had at least one practitioner with a mobile phone. Mobile phones were found in all the hospitals/clinics and the community pharmacies. Only 6% of all the outlets (n=8) had internet facilities. These included 5 community pharmacies and 3 hospitals/clinics.

Table 8. Records, tools for maintaining records as well as communicating tools in the medicine outlets.

	Hospitals/clinics **N=31** n (%)	**Community pharmacies** **N=35** n (%)	**Licensed chemical shops** **N=64** n (%)	**Total** **N=130** n (%)
RECORDS & THE TOOLS FOR MAINTAINING RECORDS				
Files/cabinets for keeping prescriptions and other patient records	31(100)	35 (100)	30 (47)	96 (74)
NHIS accreditation & records	24 (77)	15 (43)	4 (8)	43(33)
Computer with appropriate soft ware's for records	9 (29)	21 (60)	6 (9)	36 (28)
COMMUNICATION TOOLS				
Mobile/landlines	31 (100)	35 (100)	59 (92)	125 (96)
Internet services	3 (10)	5 (14)	0 (0)	8 (6)

Thirty five percent of the outlets (n=45) had copies of the latest edition of national standard treatment guidelines (STG). These included 68% of the hospitals/clinics, 46% of the community pharmacies and only 13% of the licensed chemical shops. Forty four percent (n=34) had British National Formulary (BNF) and these included 71% of the community pharmacies, 55% of the hospitals/clinics, and 3 % of licensed chemical shops. Other reference literature materials available included Pharmacy Council continuing education (CE) handouts, mainly in the licensed chemical shops; Extra pharmacopoeia mainly in the community pharmacies and others like tropical medicine and pharmacology books mainly in the hospitals/clinics and community pharmacies (Table 9).

Table 9. Reference materials available in the outlets.

	Hospitals/clinics N=31 n (%)	Community pharmacies N=35 n (%)	Licensed chemical shops N=64 n (%)	Total N=130 n (%)
National standard treatment guidelines	21 (68)	16 (46)	8 (13)	45 (35)
British National Formulary	17 (55)	25 (71)	2 (3)	44 (34)
Pharmacy council CE handouts	0 (0)	3 (9)	21 (33)	24 (18)
Extra pharmacopeia (Martindale) or B.P	5 (16)	11 (31)	0 (0)	16 (12)
Other health or pharmacology books	12 (39)	14 (40)	16 (25)	42 (32)

Overall, more than 70% of all the outlets assessed met the standards criteria for acceptable or good settings for pharmaceutical services. The infrastructure and practice settings were significantly better in the community pharmacies compared to the hospitals/clinics and licensed chemical shops (Figure 6 to 11 & Table 10).

Table 10. Rating of the infrastructure and settings for pharmaceutical and malaria control services**.**

Ratings	**Hospitals/ Clinics N=31** n (%)	**Community Pharmacy N=35** n (%)	**Licensed Chemical Shop N=64** n (%)	**Total N=130** n (%)
Poor	5 (16)	2 (6)	17 (27)	24 (19)
Acceptable	18 (58)	12 (34)	43 (67)	73 (56)
Good	8 (26)	21 (60)	4 (6)	33 (25)

Figure 6. A licensed chemical shop with poor infrastructure and practice setting.

Figure 7. A licensed chemical shop with acceptable infrastructure and practice setting but inadequate light in the premises.

Figure 8. A licensed chemical shop with good infrastructure and practice setting.

Figure 9. A hospital pharmacy with acceptable infrastructure and practice setting but inadequate lighting.

Figure 10. A good outpatient hospital pharmacy practice setting.

Figure 11. A community pharmacy with a good infrastructure and practice setting.

6.3 Availability of medicines for malaria chemotherapy and IPTp (II)

6.3.1 Non policy recommended medicines and anti-malarials not registered with FDB

Oral amodiaquine without artemisinins and chloroquine were the most highly available anti-malarials stocked in the retail outlets (i.e. community pharmacies and licensed chemical shops); but these products were mostly lacking in the hospitals/clinics. Other non-policy recommended anti-malarials that were commonly stocked in the retail outlets, particularly the community pharmacies were: dihydroartemisinin as a non-combination product, artesunate and β artemether as non-combination products, halofanthrine, pyrimethamine and cryptolepine based herbal products (Table 11).

Twenty four percent of the 130 outlets (n=31) had unregistered brands of quinine. Eighty percent of the outlets with unregistered quinine (n=25) were the retail sector facilities (15 chemical shops and 10 pharmacies). In addition 29% of all the retail

outlets including 19 licensed chemical shops and 10 community pharmacies had unregistered brands of artesunate, amodiaquine and artemisinin combination products mainly from China or India.

6.3.2 Policy recommended medicines

In January 2005, the MOH in Ghana implemented a new anti-malaria policy and treatment guidelines, where the ACTs replaced chloroquine, amodiaquine and S/P as the recommended medicines for the management of uncomplicated malaria, whilst S/P was reserved for IPTp (Table 3). In this study, Sulfadoxine/pyrimethamine (S/P) was the most common policy recommended anti-malarial stocked in all the outlets. Ninety three percent of all the outlets had stocks of S/P, however the availability of this product was higher in the retail outlets compared to the hospitals/clinics (p=0.001) (Table 11). Artesunate/amodiaquine was available in less than 50% of all the outlets. The availability of artesunate/amodiaquine was higher in hospitals/clinics (68%) compared to the community pharmacies (43%) and licensed chemical shops (27%) ($p = 0.001$). The policy recommended ACTs and quinine and were significantly more available in the community pharmacies compared to the hospitals/clinics and licensed chemical shops ($p < 0.001$). With the exception of S/P, the availability of the policy recommended anti-malarials in the licensed chemical shops was less than 45%.

Table 11. The availability of medicines for malaria therapy in the outlets.

Anti-malarial stocked	Hospitals/ clincs N=31 n (%)	Community pharmacies N =35 n (%)	Licensed chemical shops N=64 n (%)	Total N=130 n (%)
Non-policy recommended anti-malarials				
Amodiaquine tabs/suspensions	12 (39)	35 (100)	59 (92)	116 (87)
Chroroquine tabs/syrup & injections	17 (55)	30 (86)	61 (95)	108 (83)
Dihydroartemisinin tabs/suspensions/suppositories	16 (52)	35 (100)	38 (59)	89 (68)
Artesunate tabs	15 (48)	22 (63)	49 (76)	86 (66)
β artemether caps/suspension	10 (32)	28 (80)	33 (52)	71 (55)
Cryptolepine-based mixtures	0 (0)	20 (57)	37 (58)	57 (44)
Pyrimethamine tabs	4 (13)	28 (80)	12 (19)	44 (34)
Halofanthrine tabs	1 (3)	27 (77)	6 (9)	34 (26)
Pyrimethamine/sulfamethoxypyrazine tabs	2 (6)	3 (9)	7 (11)	12 (9)
Artesunate/sulphamethoxypyrazine tabs	0 (0)	9 (26)	3 (5)	12 (9)
Dihydroartemisinin/piperaquine tabs/suspension	1 (3)	5 (14)	1(2)	7 (5)
Policy recommended anti-malarials				
Sulfadoxine/pyrimethamine tabs	24 (77)	35 (100)	62 (97)	121 (93)
Quinine tabs/injections	21 (68)	27 (77)	28 (44)	76 (58)
Artesunate and/or Artemether combination products (tabs/suspensions)	24 (77)	28 (80)	18 (28)	70 (54)
Artesunate/amodiaquine tabs	21 (68)	17 (49)	17 (27)	56 (43)
Artemether/lumefanthrine tabs/suspensions	5 (16)	24 (69)	4 (6)	33 (37)
Artemether injection/rectal artesunate	13 (42)	20 (57)	3 (5)	36 (28)

6.3.3 Other commodities stocked for mosquito control in the outlets

Other commodities that were stocked in the outlets included insecticide treated nets (ITN), mosquito sprays and creams. The mosquito creams were found in more than 60% of the community pharmacies and licensed chemical shops. The ITNs were rather common in the community pharmacies and hospitals/clinics. With exception of the mosquito creams, less than 50% of all the outlets stocked the ITNs and the mosquito sprays.

Table 12. Commodities stocked for mosquito control.

Commodities stocked	Hospitals/ clinics N=31 n (%)	Community pharmacies N =35 n (%)	Licensed chemical shops N=64 n (%)	Total N=130 n (%)
Mosquito cream repellents	6 (19)	31 (89)	39 (61)	76 (58)
Insecticide treated bed nets	18 (58)	23 (66)	21 (33)	62 (48)
Mosquito spray insecticides	7 (23)	21 (60)	19 (30)	47 (36)

6.3.4 Adherence to policy recommendations when supplying medicines

More than 50% of the outlets (n=73) did not adhere to policy when selecting medicines to be supplied for malaria therapy. Non adherence was higher in the licensed chemical shops (n=56) compared to the community pharmacies (n=13) and hospitals/clinics (n=4) ($p < 0.001$). Only 8% (n=10) of all the outlets including 9 hospitals/clinics and 1 chemical shop strictly adhered the policy, when selecting medicines for malaria therapy. Thirty six percent (n= 47) including 22 community pharmacies, 18 hospitals/clinics and 7 chemical shops partially adhered to the policy on drug selection for malaria therapy (Figure 12).

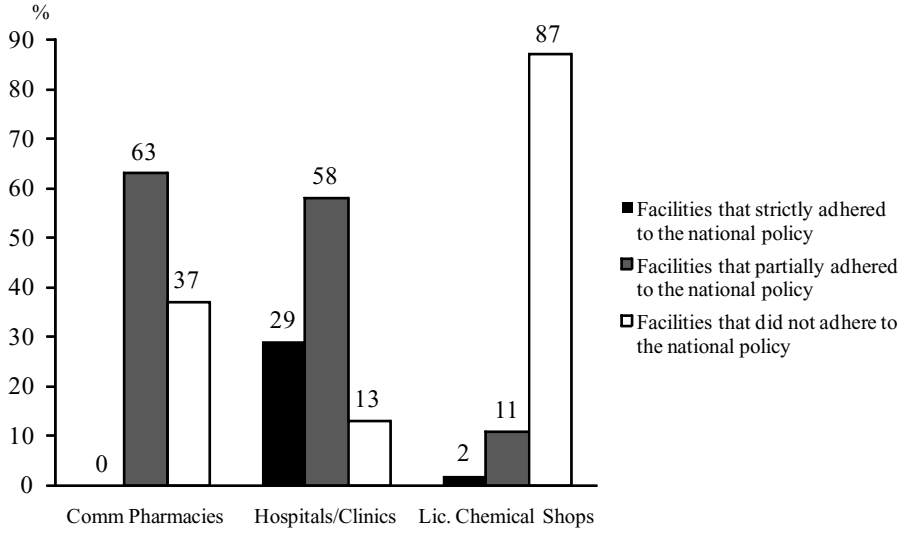

Figure 12. Adherence to policy recommendations when selecting anti-malarials for malaria chemotherapy or IPTp.

6.4 The staff resources, their knowledge and practices for malaria therapy

6.4.1 Staff resources in the outlets and their professional status

The total number of workers employed in the 121 medicine outlets assessed was 481 (Table 13). One hundred and sixty seven were in hospitals/clinics, 163 in community pharmacies and 151 in licensed chemical shops. Fifty three percent of all the employees had no professional training as health workers. Forty four percent were trained professionals and 3% were students. The hospital/clinics significantly had a higher number of professional staff per outlet compared to the retail outlets ($p<0.001$).

Of the 481 workers, only 154 were available for the knowledge and practices assessment. This was made up of 46 practitioners in hospitals/clinics, 50 in community pharmacies and 58 in licensed chemical shops. Fifty nine percent of the practitioners assessed were non professionals and 41% professionals, reflecting the proportion of the total professionals and non professional staff in the medicine outlets (Table 13).

Table 13. Staff resources in the medicine outlets and their professional status

Medicine outlet practitioners	Hospitals/clinics N=30 n (%)	Community pharmacies N=35 n (%)	Licensed chemical shops N=56 n (%)	Total N=121 n (%)
Professionals	**130 (78)**	**74 (45)**	**8 (5)**	**212 (44)**
• pharmacy tech*	96	23	4	123
• pharmacists	23	48	0	71
• nurse/midwifes	11	3	4	18
Intern/student pharmacists	**7 (4)**	**90 (6)**	**0 (0)**	**16 (3)**
Non professionals	**30 (18)**	**80 (49)**	**143 (95)**	**253 (53)**
• pharmacy/chemical shop assistants	27	71	85	183
• licensed chemical sellers	0	0	53	53
• non pharmacists proprietors	1	8	5	14
• cleaner	2	1	0	3
Total	**167 (100)**	**163 (100)**	**151 (100)**	**481 (100)**

Pharmacy tech* represents pharmacy technologists/technicians

6.4.2 Knowledge, skills and practices of staff for malaria therapy

Of the practitioners assessed, 83% knew the mode of malaria disease transmission (Table 14). Eighty seven percent knew and could also recognize the common signs and symptoms of uncomplicated malaria. Sixty four percent could recognize the danger signs of complicated malaria and indicated that they will refer such cases to appropriate institutions for better care. Eighty one percent could advice clients with the right information on behaviors and practices for malaria prevention. Just 38% were well informed about current initiatives and strategies for malaria control in Ghana. In addition only 21% knew about IPTp, and 20% were adequately knowledgeable and skilled to identify and manage uncomplicated malaria with ACTs.

Table 14. The practitioner's knowledge skills and practices for malaria therapy.

Knowledge/ practice skills assessed	Hospitals /clinics N=46 n (%)	Community pharmacies N=50 n (%)	Licensed chemical shops N=46 n (%)	Professionals N=63 n (%)	Non professionals N=91 n (%)	Total N=154 n (%)
Symptoms of uncomplicated malaria	44 (96)	45 (90)	46 (79)	59 (94)	76 (84)	135 (87)
Malaria transmission	42 (91)	46 (92)	40 (69)	58 (92)	70 (77)	128 (83)
Malaria prevention	39 (85)	45 (90)	40 (69)	56 (89)	68 (75)	124 (81)
Symptoms of complicated malaria	36 (78)	38 (76)	25 (43)	51 (81)	48 (53)	99 (64)
Malaria control initiatives	28 (61)	21 (42)	9 (19)	43 (68)	15 (16)	58 (38)
IPTp	20 (43)	10 (20)	2 (3)	30 (48)	2 (2)	32 (21)
Management of malaria with ACTs	16 (35)	12 (24)	3 (6)	27 (43)	4 (4)	31 (20)

The professional staff members in the various medicine outlets were rated higher than the non professionals on all measures (Figure 13). Also the staff in hospitals/clinics had better knowledge and were more skilled than those in community pharmacies and licensed chemical shops ($p<0.001$).

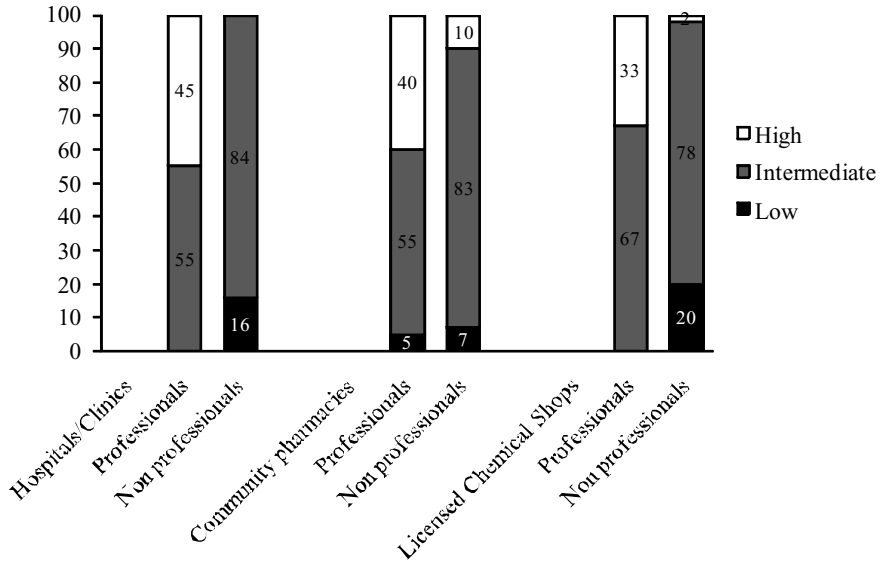

Figure 13. Rating of the knowledge and practice skills of the practitioners according to their professional status.

7 DISCUSSION

7.1 Appropriateness of self-care and the role of medicine outlets

In the anti-malarial utilization study, in which the appropriateness of self-care and health-facilities based therapy of malaria was studied, a high level of 'incorrect use' of the anti-malarials (with regards to the dosage and duration of therapy), and consequently treatment failures with the self-care were observed among many patients. Later these ended in the hospital or polyclinic as cases of moderate to severe or complicated malaria. Incorrect usage of the anti-malarials was highest among those who used left-over medicines at home or those who obtained their anti-malarials from retail outlets, particularly the licensed chemical shops. On the contrary, both clinical and humanistic outcomes to malaria therapy in the rural hospital and the city-based polyclinic were good for the patients that were managed in accordance with the malaria therapeutic guidelines available at the time, which was also based on prevailing evidence of safety and efficacy of those medicines (Awoonor-Williams et al 2004, Robertson et al 2007, Herxheimer et al 2008). Treatment outcomes, similar to what was observed in the 2002 study, had been reported by some Ghanaian researchers and their international collaborators, on patients who adhered to pre-packed oral dosage regimen of chloroquine, which was then the national recommended medicine for malaria therapy (Ansah et al 2001). It was then suggested that in order to improve the quality of self care or home-based management of malaria, as a way of increasing prompt access to effective treatment for malarial disease, there was the need for pragmatic interventions to be adopted to empower the general public and medicine outlet practitioners, on safe and responsible use of anti-malarials (Guerin et al 2002, Jones 2003, Vain et al 2007).

7.2 Infrastructure and settings for pharmaceutical services

The majority of the medicine outlets involved in the year 2007 field study, including those in the retail sector, satisfied the minimum standards criteria for the infrastructure and settings for pharmaceutical services. The community pharmacies relatively had a

better infrastructure and practice settings compared to the hospitals/clinics and the licensed chemical shops. However, close to a fifth of the medicine outlets failed to meet the minimum standards criteria for the infrastructure and practice settings. The majority of those were licensed chemical shops, which are also the most predominant medicine outlets in the rural and deprived areas in the country (Agyepong et al 1999, Cohen et al et al 2004, Goodman et al 2005). For the medicine outlets, and particularly those in the retail sector, to be confidently involved in national and community-based initiatives for malaria control, or other health initiatives against diseases of preventable and treatable causes; the infrastructure and practice settings must be conducive and conform to acceptable standards for pharmaceutical and primary care services (Latif 2000, WHO 2004, Goodman et al 2007a). The outlets must also be resourced with appropriate medicines, operational tools and staff that are motivated to provide safe services, whilst adhering to national regulations and policies for health and pharmaceutical services (SEAM 2003, Goodman et al 2004, Backmann et al 2008).

Among the areas in which most of the outlets satisfied the standard criteria for the infrastructure and practice settings included space, lighting and ventilation. Most of the outlets had adequate space, lighting and well ventilated premises that guaranteed visibility, free circulation of air and ambient temperature conditions that were suitable for the products stocked on the shelves. A few of the outlets however had poor lighting conditions, of which many were hospitals/clinics and licensed chemical shops. Close to half of all the medicine outlets also did not have refrigerators for medicines that required cold storage, including artemisinin-based suppositories. In addition, very few had functioning air conditioners, which could create the most ideal conditions for the storage and supply of medicinal products in a hot climate country like Ghana (Russel 2003, Sekhri 2005, Backmann et al 2008). In order to preserve the quality and therapeutic integrity of pharmaceutical products stocked and supplied from medicine outlets, appropriate temperature and storage conditions should be maintained at all times in the outlets; also patients/clients receiving medicines from the outlets should be adequately advised on the medicines and the conditions in which it must be stored (ASHP report 1992, Christensen et al 2006, Vain et al 2007).

Among the areas in which most of the outlets fell short in the assessments, included cleanliness or tidiness of the settings, the extent of hygienic practices, and assurance of privacy during counseling. More than half of the outlets had untidy premises, showing as dust and cobwebs on the walls, shelves and some of the pharmaceutical products displayed on the shelves. Untidy practice environment, unclean dispensing tools and dust on pharmaceutical products could facilitate product degradation and hence a decrease in biological activity and/or therapeutic effect. Efforts should therefore be made to improve the level of cleanliness and hygienic practices in medicine outlets to preserve product quality (ASHP report 2002, FIP 2005, Quick et al 2005).

Regarding patient confidentiality: apart from the community pharmacies, many of the outlets did not have any place earmarked for counseling that guaranteed the privacy of patients/clients during interaction with medicine outlet practitioners on their health or medications. To assure privacy and patient confidentiality it may be necessary for the owners or managers of the medicine outlets to invest in infrastructural arrangements and create a separate area for counseling purposes. In a study in the mid 1990's that sought to explore customer feedback as a means to improve pharmacy services in Finland, it was shown that lack of privacy or client confidentiality was one of the major distractions that adversely influenced the utilization of pharmacy services (Airaksinen 1996).

7.2.1 Packaging of anti-malarials to be dispensed

In most of the outlets, non-blister pack anti-malarial tablets or capsules were packaged with the aid of dispensing spoons. Anti-malarial suspensions were also dispensed mainly in the manufacturer's original pack; whereas anti-malarial tablets/capsules were packaged and dispensed in airtight plastic envelopes or paper envelopes. These practices of packaging pharmaceuticals for dispensing were in line with the standard procedures and pharmaceutical practices in Ghana (GNDP 2004). However in few chemical shops, chloroquine syrup was re-packaged and dispensed as aliquots in bottles other than the manufacturer's original pack. Suitability of the materials for packaging and storing of pharmaceuticals both in the medicine outlets, and

at home by the patients/clients is as important as the environmental and temperature conditions maintained in the outlets to assure the quality, safety and therapeutic integrality of the pharmaceutical product. To safeguard the health and safety of the society and the individual clients, it is important to ensure that appropriate materials are utilized to package and to store pharmaceuticals that are kept in the medicine outlets or dispensed to be utilized by clients at home (Quick et al 2005, FIP 2005).

7.2.2 Tools to aid the identification of malaria cases and optimization of anti-malaria therapy

Very few of the retail outlets had a clinical thermometer, which was readily available and used by clinicians in the hospitals/clinics to assess the temperature of patients, whilst trying to diagnose malaria infection. Also none of the retail outlets had rapid diagnostic kits or any other diagnostic instrument to confirm the febrile illnesses that were usually managed presumptively as malaria in the outlets. Presumptive management of fever as malaria, without objective evidence of the presence of malaria parasites in the affected individual may be associated with over-diagnosis, and could possibly lead to costly and unnecessary exposure of potent anti-malarials to individuals who may not need it (Goodman et al 2004, A-Elgayoum et al 2009). Presumptive therapy with anti-malarials could also imply wrong therapeutic intervention for other febrile conditions like pneumonia or related bacterial infections that would require antibiotics for appropriate therapeutic management (Chandler et al 2008, A-Elgayoum et al 2009, Dodoo et al 2009). In order to optimize community-based approaches to promptly identify and manage malaria cases as means of reducing malaria morbidity in Ghana, appropriate diagnostic tools should be available in the retail outlets and the practitioners must be trained to effectively use such tools to aid identification of malaria cases. This would enable the application of specific therapeutic interventions to treat uncomplicated malaria cases, and to refer complicated and non-malaria febrile conditions to appropriate facilities for the best management (Ridley 2003, Winstanley et al 2004, Boggild et al 2009).

Apart from the non-availability of malaria diagnostic kits, many of the retail outlets did not have weighing scale and thus mostly estimated anti-malarial dosages using the patient's age or body size instead of actual weight, with the dosages expressed in mg/kg body weight. When dosages of anti-malarials are not correctly estimated, drug therapy could result in adverse effects and hence poor adherence to therapy in case of overdosage, or reduction in therapeutic efficacy or treatment failure in case of underdosage (Schnipper et al 2006, Herxheimer et al 2008). Considering the burden of malaria and the existence of multi-drug resistant parasites in Ghana it would be important for medicine outlets, and particularly those in the retail sector, to take the necessary steps to ensure that appropriate tools are available, and correctly utilized to optimize the management of malaria from the outlets (Griffith et al 2007, RBM 2008). In so doing, it would make public health sense to actively involve medicine outlets and their practitioners in all national initiatives for malaria control, in order to protect the health and save the lives of vulnerable individuals and poor populations at risk in Ghana (Sekhri 2005, Goodman et al 2007a, Smith 2009b).

7.2.3 Records maintained in medicine outlets and tools for communication

Almost all the medicine outlets, except a few chemical shops had books, files and cabinets for keeping records including prescriptions, drug purchase invoices and daily sale records. However, less than a third of the outlets, with the majority being community pharmacies, had computers that were used to store some of the records. Effective documentation on medicines stocked and supplied from the outlets as well as documentation of patients/clients profile with adequate information on demographics, health and medication history, etc could be a rich source of data for research to enhance medicines utilization, and pharmaceutical services in medicine outlets. However, in many developing countries including Ghana, such records are not properly maintained or adequately utilized as sources of research data (Anderson 2002, Smith 2004, de Castro et al 2007). To facilitate research on practices in medicine outlets and thus generate appropriate evidence to inform policies and guidelines for pharmaceutical

services, records maintained in the outlets should be standardized to serve as quality source of data.

On tools for communication in the outlets; nearly all the practitioners encountered during data collection had mobile phones. Some of the outlets in the cities also had internet facilities, which they were using as source of drug information to enhance their services. It is important that medicine outlets in developing countries are encouraged to computerize their operations, and make use of available technology including mobile phones and other communication tools to aid services and information management (Syhakhang et al 2001, Siddiqi et al 2005). An example of such venture is the linking of medicine outlets and their practitioners with competent health providers within or outside their locality, and/or drug information centers through the internet or telephone consultations to strengthen pharmaceutical services and case referrals (Awoonor-Williams et al 2004, Sanders et al 2005, Reid 2006).

7.2.4 Reference materials and its relevance to pharmaceutical services

All the different types of medicine outlets assessed had one form of reference material or another for the practitioners to consult, in case of doubt about which product to select or dosage to use to treat specific patients. The reference materials ranged from standard treatment guidelines (STG), British National Formularies (BNF) and various pharmacopeias (e.g. B.P, Martindale) to handouts from continuing education programs as well as various health and pharmacology books. The STG, BNF, books and pharmacopeias were mostly found in the hospitals/clinics and community pharmacies whereas the continuing education handouts were found mostly in the licensed chemical shops. It is encouraging that medicine outlets in the Ghanaian health system are adopting a culture of stocking reference literature and treatment protocols to support their services. However, what is important is that these reference materials must be current and should provide information that is reliable and relevant to health or pharmaceutical needs of the society (Christensen et al 2006, de Castro et al 2007). In this study, less than half of the outlets had current edition of the national STG, and the availability was particularly poor in the retail outlets. To enhance adherence to national

treatment guidelines for malaria therapy and other common diseases, it should be mandatory for the medicine outlets to keep a current edition of the STGs and consulted regularly to aid primary care services (Ansah et al 2001, Abuya et al 2009).

7.3 The availability and accessibility of medicines and other commodities

7.3.1 Malaria prevention

Anti-malarials available to be supplied for malaria prevention in the outlets included Sulfadoxine/Pyrimethamine (S/P) and pyrimethamine as a non-combination product. S/P was the most commonly stocked anti-malarial in all the different outlets. S/P has shown to be effective and thus recommended in national policies of many countries in sub-Saharan Africa, including Ghana for Intermittent Preventive Therapy (IPT) in both infants and pregnant women (Hommerich et al 2007 Tope et al 2007). However, in this study, S/P was rather observed as being used presumptively for treating fevers suspected to be malaria. This raises concern about the possibility of S/P becoming soon ineffective as a prophylactic agent in Ghana, as a result of resistance. Already, *plasmodia* resistance and also lack of therapeutic efficacy to S/P for malaria has been reported in some parts of sub-Sahran Africa (Baird 2005, Goodman et al 2007a). The emergence of the resistance strains has been largely attributed to its widespread accessibility and indiscriminate use at home and in the community for malaria therapy (Goodman et al 2004, Hill et al 2006). In order to preserve the effectiveness of S/P as a prophylactic agent for malaria in pregnancy, efforts should be made to discourage its widespread use for malaria treatment, more so when its efficacy is doubtful (Goodman et al 2004, Baird 2005). It may also be necessary now for anti-malaria policy makers, researchers and the pharmaceutical manufacturers to collaborate and look for a suitable alternative to S/P as a prophylactic agent, ‘in case of future loss effectiveness’ in Ghana. IPTp is a proven effective intervention strategy for reducing malaria morbidity and mortality among pregnant women and their new born infants in sub-Saharan Africa (Morel et al 2005, Bate et al 2009).

Most of the community pharmacies and a few of the hospitals/clinics and licensed chemical shops also did stock pyrimethamine as a non-combination product, and was supplied for use as a chemo-prophylactic drug. Pyrimethamine and other antifolates as non-combination products have also been found to be still used for malaria prophylaxis in other neighboring West African countries (Tope et al 2007). However, the evidence available indicates that these products were ineffective in protecting users against malaria infections, unless it was used in combination with a sulfonamide as in S/P, or naphthalene as in atovaquone-proguanil (Morel et al 2005, Tope et al 2007). In order not to derail the ongoing initiatives and programs for malaria control, the laws on pharmaceutical services and medicines management must be enforced to stop the stocking and use of ineffective products for malaria prophylaxis in the health system.

Other commodities that were available in the outlets for malaria prevention through vector control included mosquito creams, sprays and ITN. The availability of these commodities were higher in the community pharmacies compared to the hospitals/clinics and the licensed chemical shops. Very few of the hospitals/clinics had mosquito sprays and creams available for use as an interventional tool against mosquito contacts. This is not surprising since creams, sprays and other mosquito insecticides/repellents are usually sold in retail medicine outlets or supermarkets in sub-Saharan Africa. What was interesting was the low availability of ITNs in the hospitals/clinics compared to the community pharmacies, since the hospitals/clinics are the main distributing channels for free ITNs supplied by UNICEF and other donors to pregnant women and mothers with children who are five years of age and below in disease endemic areas (WHO 2008). The design of this study however, did not include investigation on how the ITNs in the outlets were sourced, and whether they were sold or distributed for free to patients/clients. The availability and distribution of ITNs in hospitals/clinics and other public sector institutions must therefore be evaluated further in order to provide information on the status and impact of the national initiative regarding the distribution and use of ITN and other tools for malaria control, as has been done for Ruwanda, Ethiopia and Zambia (Coll-Seck 2008, Grabowsky 2008, Skeketee 2009). In order to promote greater access and use of ITN in a larger section of the population, the community-based retail outlets, which are easily accessible to the public

in both the rural and urban areas, may be used as additional distribution channels in addition to those in the public sector (Butler 2004, Vian et al 2007, Feachem et al 2009). The implementation of any such program however, must be well monitored and controlled to prevent exploitation and abuse by the practitioners in the private sector, to the detriment of expected public health benefits (Trapet al 2001, Goodman et al 2007a, Smith 2009b).

7.3.2 Malaria treatment

The availability of policy recommended anti-malarials were higher in the hospitals/clinics and community pharmacies, which are largely urban based. However, the availability of policy recommended medicines, and in particular the artemisinin-combination products (ACTs) were low in the licensed chemical shops, which are predominantly rural or peri-urban based. Generally, the ACTs were not available in most of the outlets assessed, rather chloroquine, amodiaquine (without artesunate), and S/P which are known to be less effective as chemotherapeutic agents were highly available, particularly in the retail outlets (Guerin et al 2002, Koram et al 2005, Dodoo et al 2009). The poor availability of ACTs is most likely to influence the selection and use of the highly available ineffective alternatives for the management of uncomplicated malaria cases. This would eventually lead to treatment failures, and undermine the current initiatives that are being undertaken to promote prompt access and use of effective medicines for malaria therapy, and thus further worsen the problem of morbidity and mortality from malaria in Ghana, which could spread to other countries in the sub-region (WHO 2004, WHO 2008).

Artesunate/amodiaquine, the first-line ACT was commonly found in the hospitals/clinics, whereas artemether/lumefanthrine, the second line alternative was more commonly stocked in the community pharmacies. The availability of all forms of ACTs in the chemical shops was very poor. The explanation for these observations may be that the hospitals/clinics, which were mostly public or faith-based institutions, obtained their anti-malarial stocks from government funded medical stores that keep only the essential medicines listed in the national formulary. Many of the

hospitals/clinics were also NHIS accredited, and were thus obliged to stock and supply the least expensive and first line ACT for the therapeutic management of uncomplicated malaria (GNDP 2004, Dodoo et al 2009, Ridde et al 2009). The retail sector outlets however, mainly use private wholesalers or the local manufacturers as their sources for anti-malarials. In addition, stocking of products in retail outlets are mostly market driven and may thus be dependent on the frequency of requests or purchasing power of the clients that visit the outlets (Unger et al 2006, Cohen-Kohler 2007). This probably explains the pattern of the availability of ACTs in the outlets assessed. In Ghana, anti-malarials and other essential pharmaceutical products that are accessed from medicine outlets are mostly financed out of pocket, except in the facilities that are accredited as service providers for NHIS. Thus the clientele of the chemical shops being largely rural based, and most likely to be poor, may not be able to afford the ACTs which are about 10 times more expensive than the locally manufactured or generic brands of the most stocked, but ineffective alternatives (Goodman et al 2004, Bate et al 2009, Goodman et al 2009). The clientele of the largely urban based community pharmacies, however, were likely to be rich in socio-economic terms, and may be willing to pay for the more expensive artemether/lumefanthrine, which was then perceived to be more tolerable and effective than artesunate/amodiaquine. Available evidence however suggests that both ACTs are equally safe and effective (Koram et al 2008, Dodoo et al 2009). Public education must therefore be intensified by health stake holders, including practitioners in the pharmaceutical sector to improve the acceptability and thus appropriate use of artesunate/amodiaquine by both the public and prescribing clinicians.

Apart from chloroquine and amodiaquine, oral dosage forms of several artemisinins as non-combination products (e.g. dihydro-artemisinin, artesunate and β artemether) were commonly available in the retail outlets and particularly the community pharmacies. Other anti-malarials that were commonly stocked in the retail outlets included halofanthrine, and cryptolepine based herbal preparations. To avoid indiscriminate prescription and use of artemisinins as monotherapy for self medication at home or presumptively for fevers in health facilities, and thus create suitable conditions for the emergence of resistant parasites against the most effective anti-malarials in recent times (Guerin et al 2002, Goodman et al 2007a, Abuya et al 2009);

every effort must be made by all concerned to discourage medicine outlets from stocking oral artemisinins as non combination products. Pharmaceutical importers and local manufacturers must also be discouraged from importing or producing oral formulations of non-combination artemisinin products. The artemisinins have short half life and are thus rapidly eliminated from the body when used alone for chemotherapy. The available evidence shows that their use is associated with high rate of recrudescence, and could precipitate the selection of resistant mutants with continuous short duration of exposure to the *plasmodia* parasites in high transmission areas (Guerin et al 2002, Kingwell 2009). Thus the artemisinins must be used appropriately, and in combination with other products that have longer half life, and thus could sustain the anti-malarial effects once the artemisinins are eliminated from the body (Ridley 2003, Eckstein-Ludwig et al 2009). Already reports of *falciparum* strains that are resistant to artemisinins have been identified along the Thailand-Cambodia border, and it is feared that the artemisinin resistance could spread to sub-Sahran Africa, if care is not taken to regulate and ensure the quality of use of the medicine for malaria therapy (Bate et 2009, Feachem et al 2009).

Regarding halofanthrine, its safety and cost effectiveness as an anti-malaria in resource poor settings has been questioned and is thus excluded from the list of anti-malarials in the national formulary (Carme et al 1993). Cryptolepine based herbal products have long been shown to have anti-malaria activity, but sound scientific evidence of their effectiveness as monotherapy or in combination with other anti-malarials in clinical trials or population based studies are lacking (Houghton et al 2003, Bennet et al 2008). Herbal products with known biological activity against *plasmodia* should therefore be evaluated further in well designed scientific studies, and incorporated into national formularies if proven to be safe and effective. In order to minimize wastage and ensure efficient use of medicines in resource limited countries, the private sector outlets must be encouraged to limit their stocks to the most essential medicines that are safe, affordable, and necessary to meet the health needs of both individuals and the entire society. The quality of practices in the private sector should also be improved so that more medicine outlets could be accredited as service providers for NHIS in the health system, to make it easier for people to access important

medicines for the control of malaria and other common public health problems without out of pocket payment (Trap et al 2001, Guerin et al 2002, Vain et al 2007, Eckstein-Ludwig et al 2009).

In addition to the low availability of proven effective and policy recommended anti-malarials in the most accessible outlets, there were also unregistered brands of quinine, amodiaquine and artemisinins either alone or in combination with amodiaquine. Most of the unregistered medicines were imported from Nigeria or Asia, and specifically from China and India. The quality of those products was questionable and their use is most likely to be associated with health and safety concerns. To avoid exposure to ineffective and unsafe medicines for malaria control, practitioners in medicine outlets and the pharmaceutical sector in general must be targeted with appropriate education and regulatory interventions, and encouraged to collaborate with other stake holders to weed out products of questionable efficacy and safety status from the health system (Butler 2004, Ndomondo-Sigonda et al 2005, Smith 2009b).

7.3.3 Adherence to policy when choosing anti-malarials for chemotherapy or IPTp

Very few of the outlets, mainly hospitals/clinics strictly adhered to the national policy recommendations for the supply of medicines for malaria therapy. All the outlets that strictly adhered to policy were accredited as service providers for NHIS. A third of the outlets, mainly community pharmacies and hospitals/clinics partially adhered to the national policy for malaria therapy. Adherence depended on whether they were dispensing prescriptions for patients covered by NHIS or for clients who were willing to pay the full cost of the medicines. None of the non adherent outlets were accredited as service providers by the National Health Insurance Council. Ensuring NHIS accreditation to a larger number of private sector medicine outlets could be an efficient way to promote provider adherence to malaria treatment policies and by extension, access of a greater number of individuals in the Ghanaian population to effective medicines for malaria control.

Other means of facilitating access to effective medicines for malaria control would be to support the local pharmaceutical industries and the retail sector outlets, to increase

the availability of quality, safe and affordable anti-malarials that are listed in the national formulary, and ensure its efficient use both at home and in the health facilities. This could be done by supporting the importation and also waving the tariffs or taxes on raw materials and excipients that are needed for the production of important or essential anti-malarials (Cohen et al 2005, Cohen 2007, Bate et al 2009). The quality control and standard operating procedures in the manufacturing process must also be strictly followed, so that locally manufactured anti-malarials are of acceptable safety and quality standards. Medicine outlet practitioners must also be adequately equipped with the requisite training and skill to ensure the management, supply and appropriate use of the medicines (Steketee 2009). Access could further be enhanced by exploring innovative and cost-effective initiatives through private-public partnership to finance, source and distribute adequate stocks of appropriately packaged and affordable anti-malarials of the desired quality to all medicine outlets in the health system, and not only those in the public sector (Penchansky et al 1981, Quick et al 2005, Goodman et al 2009).

The scope of this study could not allow all the possible reasons for provider non-adherence to anti-malaria policy recommendations to be identified. The unanswered questions bordering on non-adherence to policy, regarding the selection and supply of anti-malarials and other medicines needed for the management of common public health problems must be studied further on a national scale to unearth the answers, especially in the outlets that are registered as service providers for NHIS. The design for such studies must be more analytical and qualitative in nature to obtain much more information, to compliment or strengthen the evidence from such a descriptive and quantitative approach adopted in this study. Quality evidence from such studies would allow appropriate interventions to be initiated to address the major barriers to the implementation of evidence-based policies that are designed to manage or control crucial public health problems that impacts negatively on the health, quality of life and socio-economic development in the country (Sachs et al 2002, Hlongwana et al 2009, Steketee 2009).

7.4 Staff resources and their training as pharmaceutical service providers

More than half of all the staff members in the outlets assessed had no professional training in health or pharmaceutical services provision. The majority of the non-professional employees were working in the retail outlets. This evidence is similar to others already published about retail medicine outlet practitioners in sub-Saharan Africa (Goodman et al 2004, Goodman 2007a, Smith 2009a). This may be part of the reason why some experts are skeptical about including the retail outlets in the implementation of public health initiatives like the Roll Back Malaria initiative in sub-Saharan Africa (Syhakhang et al 2001, Smith 2009a). However, the retail outlets are commonly visited for health advice and primary care services in many parts of sub-Saharan Africa (Houghton et al 2001, Smith 2001, Guerrin 2002, Goodman et al 2007a). Besides, the retail practitioners are normally familiar and trusted by the inhabitants in the communities in which they are located. They also operate for long hours and serve as convenient and easily accessible sources for medicines and treatment of malaria and other common diseases (Smith 2001, Smith 2004, Viberg et al 2007). To promote public health, it may be prudent for the retail practitioners to be trained appropriately and motivated with incentives and regulation to provide safe services; and thus complementing health services delivered in the public sector. The training programs must be well structured to adequately equip every cadre of practitioner to be able to practice in accordance with policies and best practice guidelines, and with the health and safety of clients as the goal for service delivery (Mbwasi 2005, Goodman et al 2009b, Smith 2009a).

7.4.1 Knowledge, skills and practices of staff for malaria control

Nearly all the practitioners assessed in the outlets (including professionals and non-professionals) were knowledgeable about the mode of malaria disease transmission and could also counsel clients with the right information for disease prevention. Many could also identify cases of both complicated and uncomplicated malaria, but only a few (mainly professionals) knew about the current initiatives for malaria control, and very

few were adequately skilled to manage malaria cases as recommended by national guidelines. The focus of any future interventions to improve malaria control practices in medicine outlets must therefore include the development of practitioners' competencies in malaria case management. Training of practitioners to improve their knowledge on current strategies for malaria control including IPT in vulnerable populations like infants and pregnant women must also be considered as priority.

In this study, it was observed that medicine outlet practitioners in the hospitals/clinics tended to participate in training programs that were organized by public institutions like the National Malaria Control Programme and Ghana Health Service. Those in the retail outlets were largely trained by Pharmacy Council and medical representatives of pharmaceutical marketing or manufacturing companies. Each of the training programs was run separately with no co-ordination or collaboration between the respective training institutions. Institutional collaboration in public health intervention programs for medicine outlets and their practitioners may help to achieve greater efficiency in delivery, coverage, sending consistent messages and obtaining best outcomes for improved practices. (Butler 2004, Morel et al 2005, Sekhri 2005)

7.5 Methodological considerations and limitations

In the 2002 health facilities-based anti-malarial utilization study, almost half of the participants involved in the study (mostly ambulatory patients with mild malaria illness) were lost to follow up for therapeutic outcomes assessment. It was therefore difficult to assess whether those patients responded positively to the anti-malaria therapy or not, though they may have returned to the health facilities if their conditions had worsened after the anti-malaria therapy. The loss of follow up occurred, despite the fact the study was designed to be able to collect data prospectively. This was thought to be the most pragmatic approach in such challenging settings, to generate adequate data about the use of anti-malarials by patients and its relation to treatment outcomes, whether from self-care or in the health facilities. However, all the study participants admitted and treated for moderate to severe or severe malaria were effectively followed up for therapeutic outcomes assessment. The results obtained then provided a good indication about the

quality of use of anti-malarials obtained from licensed medicine outlets, and thus was the basis for the latter assessment the staff resources in the medicine outlets in the health system and their practices for malaria control.

The difficulty in tracing some of the participants that visited the facilities as ambulatory patients may be due to the poor address system and the high rate of migration of individuals in search of quality health care within the country, and in the regions. The two health care facilities that were used in this study are perceived as some of the best resourced in the region for health services. Health authorities in Ghana and the appropriate local government administrators should therefore put in place health information management systems that would ensure effective follow up for patients that are treated at health facilities or who visited retail medicine outlets for some primary care services. Instituting such health information management systems, and also improving the address situation in the country could facilitate health services and medicines management research in health facilities, to inform protocols, guidelines and policies for interventions for diseases of preventable and treatable causes (Aiga 2005, FIP 2005, de Castro et al 2007).

With respect to the latter assessments on the pharmaceutical settings and practices for malaria control; a major limitation was assessing only 130 outlets in two out of the ten regions in Ghana. Coupled to this 9 outlets were also excluded from the assessment of the staff resources and their practices for malaria control. However, the design of this study ensured the inclusion of a representative range of all types of medicines outlets in the two socio-economically diverse regions in Ghana, and also involved both professional and non-professional medicine outlet practitioners in the regions. Another limitation might be using trained research assistants for the data collection and possibly some variations in the quality of data obtained; however the researcher was present in each of the outlets to supervise the entire process of data collection, and thus cross checked the information recorded on the data sheets in order to assure its quality and reliability. Also the combination of approaches including staff interviews, documentation review and observation of practices was used as a means of validating the data obtained by each of the methods. Thus, much as the study results may not represent the situation in the entire country, there is confidence that the evidence

generated in this study provides a likely reflection of the infrastructure and practice settings, the material and human resources as well as practices for malaria control in licensed medicine outlets in Ghana.

8 CONCLUSIONS

The conclusions that can be drawn from this study are:

1) There was high prevalence of 'incorrect use' of the anti-malarials that were obtained at home or in community-based retail outlets for self-care, leading to deterioration of the malaria illness and manifestation of severe symptoms, which were managed appropriately in well resourced health care institutions.

2) The basic infrastructure and settings for pharmaceutical services for majority of the outlets, including those in the retail sector were of minimum acceptable standards. By further improving the infrastructure and safety of practices in the medicine outlets, they could serve as useful alternative units in the health system, to expand access to effective interventions for malaria control.

3) There was high availability of non-policy recommended and mostly ineffective anti-malarials in most of the medicine outlets, particularly those in the retail informal sector, which were also the most dominant in the rural areas.

4) With the exception of S/P, the availability of policy recommended medicines and other tools for prevention and management of malaria was poor.

5) Very few of the outlets strictly adhered to the national policy recommendations regarding the selection and supply of medicines for malaria therapy.

6) The majority of practitioners in the outlets including both professionals and non-professionals were knowledgeable about malaria symptoms and the mode of disease transmission. Many could also advise clients with appropriate information on practices for malaria prevention.

7) Only a few practitioners were knowledgeable about the current initiatives for malaria control and also adequately skilled to manage malaria cases efficiently.

8.1 Policy implications and applicability of study findings

To be able to contribute efficiently towards malaria control in Ghana, the capacity of practitioners in the medicine outlets must be strengthened to manage malaria cases appropriately. They should also be updated regularly on current public health initiatives

and intervention strategies for malaria control. Generally, suitable interventions should be targeted towards all practitioners in the pharmaceutical sector, to improve the availability and supply of effective medicines and other commodities for malaria control**.**

The evidence generated from this study is relevant to guide the interventions that may be targeted towards practitioners in medicine outlets and the pharmaceutical sector, to enhance their contributions towards malaria control in Ghana. This study also provides suggestions on areas to research further in order to inform pragmatic interventions and policies on human resource development, medication management and health promotion practices in medicine outlets of both public and private sector facilities. Again the study provides suggestions about a role that could be played by a strengthened pharmaceutical sector in the implementation of public health initiatives for malaria control. The universities and other training institutions could also be guided by the results, to train pharmacy students and other practitioners in the pharmaceutical sector on critical public health roles for the prevention and management of malaria and other common health problems.

9 RECOMMENDATIONS FOR FURTHER RESEARCH

1) The funding, availability, distribution and supply of effective medicines and other commodities required for malaria control should be evaluated further, with more outlets from all the 10 regions in the country, in order to get more generalized information on nationwide access to effective interventions for malaria control, and its impact on population health.

2) A nationwide study (biomedical and epidemiological) on the effectiveness of S/P as a prophylactic agent for IPTp should be conducted, so that appropriate actions could be taken to review the existing policy or improve the quality of use of S/P for IPTp and IPTi.

3) New and affordable anti-malarials, including herbal products with known biological activity against *plasmodia* should be further evaluated and incorporated into national formularies if proven to be good quality, safe and effective.

4) Future studies should also look at the drug reimbursement system in Ghana, and analyse the factors responsible for its success or failure.

5) Education and regulatory interventions should be piloted to improve the safety of malaria medication management and therapeutic practices in medicine outlets. The impact of the above mentioned interventions on malaria control practices and its public health relevance must also be assessed.

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APPENDICES

Appendix 1. Definitions of terms used in the study I.

Clinical diagnosis	Diagnosis based on clinical assessment of the patient by a medical practitioner
Laboratory diagnosis	Diagnosis based on the presence of plasmodia parasites in blood film of patients
Correct dosage	Standard dosage of the anti-malaria drug recommended for complete treatment of the disease, based on mg/kg body weight and recommended in the STGs*
Wrong or inappropriate use of anti-malaria	Wrong dosage, wrong frequency and/or wrong duration of therapy
Uncomplicated malaria	Mild to moderate symptoms of malaria without complications
Moderate to severe malaria	Malaria cases with more illness and symptoms leading to being detained or admitted but without complications
Severe malaria	Malaria cases with complications and evidence of high parasitaemia
Clinical cure	Rapid resolution of signs and symptoms of malaria associated with improved well being of the patients
Treatment failure	Worsening of fever and other symptoms or death after initiation of therapy

Appendix II. Check list for the assessment of the infrastructure, Practice settings, Products and Services for Malaria Control in Medicine Outlets

Introduction and Consent

Dear Sir/Madam,

We are doing an evaluation study on Pharmaceutical Services in Ghana. Our aim is to identify some challenges to Pharmacy Practice in the country, and also to highlight the contribution of the Pharmaceutical sector to health care delivery in Ghana. We would be grateful if you could spare us some of your time to ask you questions on the Pharmaceutical sector and malaria control. Your cooperation is very much appreciated.

Name of Institution	
Area of practice (e.g. community pharmacy)	
Location	

A Appearance and hygiene within the premises

1. Does the external appearance of the premises for pharmaceutical services inspire confidence? **Yes** ☐ **No** ☐

2. Are all parts of the premises maintained in a tidy condition? **Yes** ☐ **No** ☐

3. Is/are there bins available for collecting waste? **Yes** ☐ **No** ☐

4. If yes where is/are the bin(s) kept?

Outside the shop	
Inside the shop	
Other	

5. How are wastes from the premise disposed of?

Carried to a dumping site	
Incinerated on site	
Other	

B The condition of the dispensing environment

6. Is there enough light in the premises for reading of labels, reference materials?

Yes ☐
No ☐

7. Are the premises air-conditioned?

Yes ☐
No ☐

8. Does the facility have a refrigerator?

Yes ☐
No ☐

9. Does the facility have a thermometer with temperature chart in the premises?

Yes ☐
No ☐

10. Is/are there computer(s) available in the premises for pharmaceutical services

Yes ☐
No ☐

11. Is there a private counseling area in the facility?

Yes ☐
No ☐

12. What dispensing tools are available in the premises?

Tablet counters	
Dispensing spoons	
Dispensing trays	
Others (specify)	

13. Are the dispensing tools kept clean?

Yes	
No	

14. What telephone services are available in the premises?

Mobile	
Fixed Line	
Both	
None	

15. What diagnostic tools and accessories are available in the premises

Clinical thermometer	
Weighing balance	
Kits for identifying malaria parasites	
Others (specify)	

C Pharmaceutical products and services for prevention and treatment of malaria in the premises

Drug & Strength	**Dosage form(s)**	**Source (Company & Country of origin)**	***Registered by FBD (Yes/NO)***
i. Chloroquine 250 mg eq to 150mg base			
ii. Amodiaquine 200mg			
iii. Sulfadoxine 500mg /Pyrimethamine 25mg			
iv. Pyrimethamine 25mg			
v. Halofanthrine			
vi. Artesunate 50 mg			
vii. Artesunate 200mg			
viii. β-Artermether 40mg			

ix. Dihydro-artemisinin 80mg			
x. Quinine 600mg			
xi. Cryptolepine based herbal preparation			
xii. ACTS[1] (a) Artesunate/Amodiaquine (b) Artemether/ lumefantrine (c) Other (specify)			
xiii. *Other Herbal antimalarials (Specify)*			

16. Which of the following products for malaria prevention are in stock?

Insecticide treated nets	
Mosquito repellants	
Mosquito sprays	
Others (Specify)	

17. Does the facility educate carers of children under five years of age on the use of insecticide treated nets? **Yes** **No**

18. Does the facility advise patients/clients on environmental cleanliness? **Yes** **No**

19. Does the facility advise patients/clients on use of mosquito repellants and sprays? **Yes** **No**

20. Does the facility take the patient's anti-malaria drug history? **Yes** **No**

21. Does the facility manage uncomplicated malaria therapeutically? **Yes** **No**

[1] ACT is Artemisinin combination products

22. Does the facility dispense antimalarial drugs prescribed by medical practitioners?	**Yes**	
	No	

23. Is the therapeutic management of malaria in the facility based on national protocols?	**Yes**	
	No	

24. Antimalaria drugs in the facility are dispensed in:	**Manufacturer's original pack**	
	Plastic envelopes	
	paper envelopes	
	Others (Specify)	

25. Liquid anti-malaria preparations dispensed in	**Aliquots from large volumes**	
	Packed in manufacturers' original container	
	Others (Specify)	
26. Reconstitution of powders into mixtures is done with	**Tap water**	
	Bagged filtered water	
	Distilled water	
	Boiled Water	
	Other (specify)	

27. Are NMCP modules for the prevention and treatment of malaria available?	**Yes**	
	No	

28. Are Pharmacy Council modules for the prevention and treatment of malaria available?	**Yes**	
	No	

29. Are GHS modules for the prevention and treatment of malaria available?	**Yes**	
	No	

30. Specify any other educational material that is available and relevant for the prevention and treatment of malaria

Reference Material
i.
ii.
iii.
iv.
v.
vi.

31. What type of patient records are kept in pharmacy or LCS if any?

Patient Records
i.
ii.
iii.
iv.
v.
vi.

32. Is the premise accredited as a service provider for the national health Insurance scheme?

Yes	
No	

Appendix III. Questionnaire for the assessment of the human resources, their knowledge on current initiatives for malaria control, and their practices for prevention and management of malaria

A Data on Pharmaceutical Manpower

Categories of Staff working in the pharmaceutical establishment

Approach for data collecton*: Interview*

22. What is the number of staff involved in providing pharmaceutical services?	**Cadre**	**Number**
	Pharmacists	
	Pharm. Technologists	
	Pharm. Technicians	
	Dispensing Assistants	
	Nurses	
If other, please specify here:	Other	

23. For each of the **pharmacists** working at the facility, indicate their professional qualification, institution and country where qualifications were obtained

	Qualification	Awarding Institution	Country
i.			
ii.			
iii.			
iv.			
v.			

24. For each of the **pharmacy technologists** or **technicians** working at the facility indicate their professional qualification, institution and country where qualifications were obtained

	Qualification	Awarding Institution	Country
i.			
ii.			
iii.			
iv.			
v.			

25. For each medicine **counter assistant** and licensed **chemical seller** indicate their highest educational qualification, institution and country where qualifications were obtained

	Qualification	Awarding Institution	Country
i.			
ii.			
iii.			
iv.			
v.			

26. For each medicine **counter assistant** and licensed **chemical seller** indicate whether they possess a certificate for pharmaceutical service provision

	YES	**NO**
i.		
ii.		
iii.		
iv.		
v.		

27. If the answer to question **6** above is **YES**, specify the type of certificate

---

28. How many of the following cadres have been trained in disease prevention and therapeutic management of malaria?

Cadre	Number
Pharmacists	
Pharm. Technologists	
Pharm. Technicians	
Dispensing Assistants	
Nurses	

29. Have you received any training from NMCP on disease prevention and therapeutic management of malaria? **Yes** ☐ **No** ☐

30. Have you received any training from Pharmacy Council on disease prevention and therapeutic management of malaria? **Yes** ☐ **No** ☐

31. Have you received any training from MoH or Ghana Health Service on disease prevention and therapeutic management of malaria? **Yes** ☐ **No** ☐

B Knowledge of pharmacy personnel on prevention and therapeutic management of malaria

32. Cadre being interviewed

Cadre	
Pharmacists	
Pharm. Technologists	
Pharm. Technicians	
Dispensing Assistants	
Nurses	

33. Have you heard about any global or regional initiative for malaria control? **Yes** ☐ **No** ☐

34. If the answer to question 12 above is **YES**, specify the type of the initiative

_____

35. How does one get malaria?

_____

_____

_____

36. Which of the malaria parasites is mainly responsible for malaria in Ghana?

_____

_____

_____

37. What advice do you offer clients for prevention of malaria?

_____

_____

_____

38. How would you identify or diagnose uncomplicated malaria?

_____

_____

_____

39. How would you therapeutically manage a patient with uncomplicated malaria?

_____

_____

_____

40. How do you decide on the dosage for the medicines you use for treating malaria?

Based on actual weight of patient	
Based on estimated weight of pt	
Based on age of patient	
Dosage determined by a clinician	
other (Specify)	

41. For each drug below, Find out how the practitioner counsel clients on appropriate use – **Approach:** ***Observation of practices***

Drug & Strength	Dosage	Duration of therapy	Side effects	Drug Interactions	Meal related instructions	*Treatment outcomes*
Amodiaquine 200mg						
Sulfadoxine 500mg /Pyrimethamine 25mg						
Artesunate 50 mg/200mg						
β-Artermether 40mg						

Dihydro-artemisinin 80mg						
Quinine 600mg						
Cryptolepine based herbal preparation						
ACTS[2] a) Artesunate/ Amodiaquine b) Artemether/ lumefantrine c) Other (specify)						

[2] ACT is Artemisinin combination products

Approach: *Interview of practitioner and validating with observation of practice*

42. How would you identify complicated malaria?

43. How would you deal with complicated malaria?

44. Have you heard about intermittent preventive therapy for malaria control in pregnant women?

Yes ☐
No ☐

If the answer to question 25 above is **YES**, describe what IPT entail

45. What would you give for malaria prophylaxis in pregnant women?

END. Thank you very much for your time

Appendix IV. Indicators for knowledge, skill and practices assessment.

Areas for knowledge & practice skills assessment	Medicine outlet staff output that indicate good knowledge or skill for anti-malaria service
1.Disease transmission	Knowledge of transmission through bites of infected mosquitoes
2.Counseling for malaria prevention	Advice on: environmental cleanliness, destruction of breeding sites of mosquitoes, use of mosquito repellents and sleeping under insecticide treated nets
3.Recognition of uncomplicated malaria	Knowledge of common signs and symptoms (i.e. fever, headache, chills, joint pains & sometimes vomiting) Checking for signs of fever (touch or thermometer) & Identifying the symptoms through staff-client interactions
4.Recognition of complicated malaria and referral	Knowledge of danger signs (high temperatures, convulsions, extreme weakness, severe vomiting, jaundiced or pallor indicating anemia) Identifying symptoms of complicated malaria and referring to appropriate institution
5.Management of uncomplicated malaria	Selecting Artemisinin-based combination product, effective communication of dosage instructions and encouraging feedback for outcome assessment
6. Knowledge on IPTp in pregnancy	Knowledge and understanding IPTp as intervention against malaria in pregnancy; Sulfadoxine/ pyrimethamine as drug of choice (S/P) and using the correct dosage.

Kwame Ohene Buabeng

The Role of the Pharmaceutical Sector in Malaria Control in Ghana

In this study, an assessment was made on medicine outlets, their practitioners, and their role in malaria control in Ghana. The study revealed that the infrastructure in the outlets was satisfactory but could be further improved to support safe pharmaceutical services. Shortfalls were identified regarding the human resource capacity, and the availability and supply of effective medicines. This evidence is believed to be relevant to guide public health interventions for the pharmaceutical sector and the medicine outlet practitioners in particular, to contribute efficiently to malaria control.

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